Medicines & Healthcare products Regulatory Agency

Welcome to the annual British Pharmacopoeia webinar

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

July 2026

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An RRD Company

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
- A BP customer feedback survey to be completed at the end – all participants will be entered into a prize draw for a chance to win £100

Webinar agenda

Understanding BP monograph requirements: from general monographs to system suitability

Presented by Oliver Waddington, Lead BP Scientist

What's new in the British Pharmacopoeia 2027 edition

Presented by Michael Whaley, Head of BP and Labs Team 2

An Inspector's perspective

Presented by Samuel Huff-Guelbert, GMDP Inspector

Audience Q&A

Presented by all

Close

British Pharmacopoeia

Medicines & Healthcare products Regulatory Agency

Understanding BP Monograph requirements

From general monographs to system suitability

Oliver Waddington

July 2026

What you will learn today

- How to interpret BP monographs beyond the product text.
- Where to find key pharmacopoeial requirements.
- How General Notices, appendices and supplementary chapters are applied in practice.
- Answers to common questions we receive.

The full BP compliance framework

Layers:

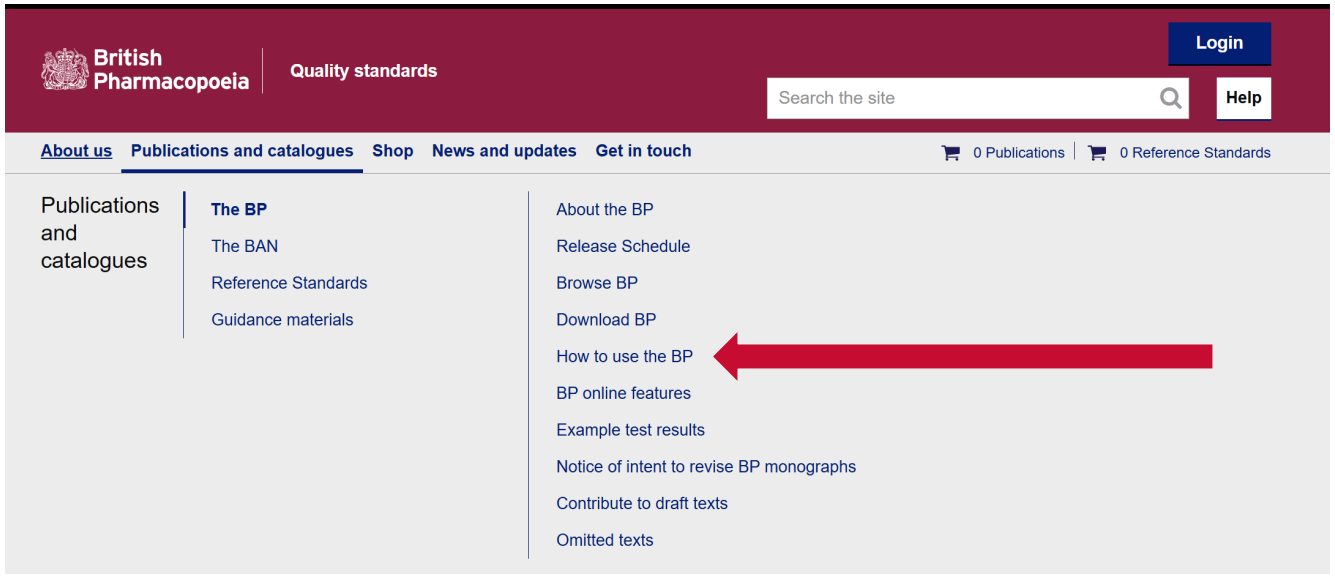
1. General Notices (mandatory overarching rules)
2. General monographs (formulated preparations)
3. Product (and substance) monographs
4. Appendices (methods and system suitability)

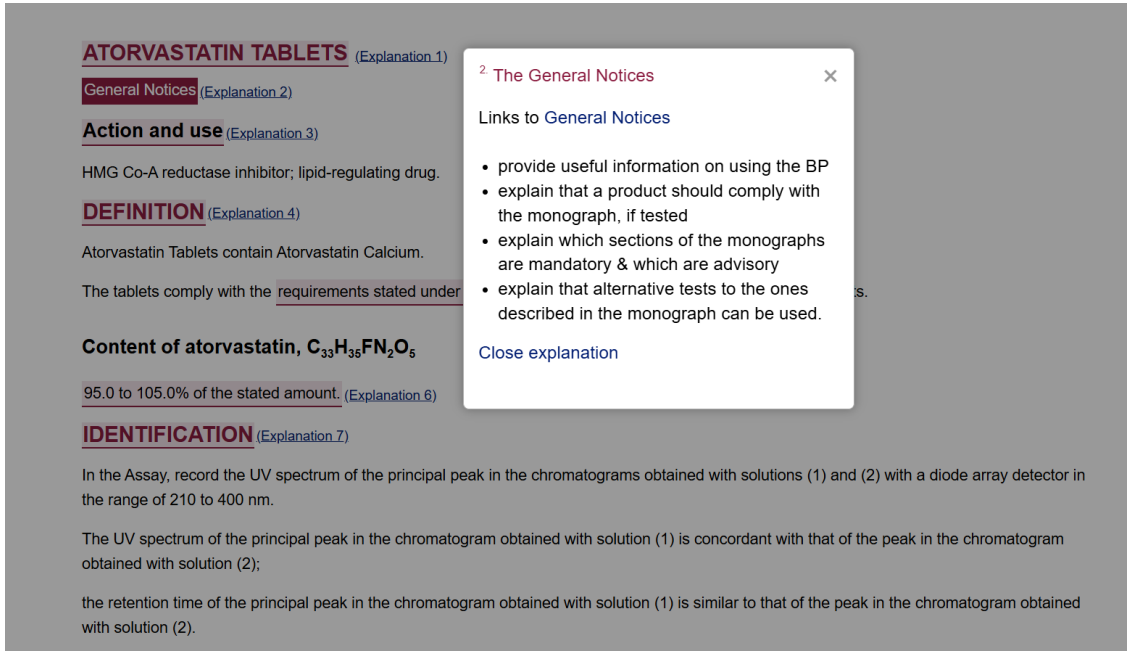
5. Supplementary chapters (supporting guidance)

Key message – A product monograph is only one piece of the compliance framework

Contents

How to use the BP





[How to use the BP - British Pharmacopoeia]

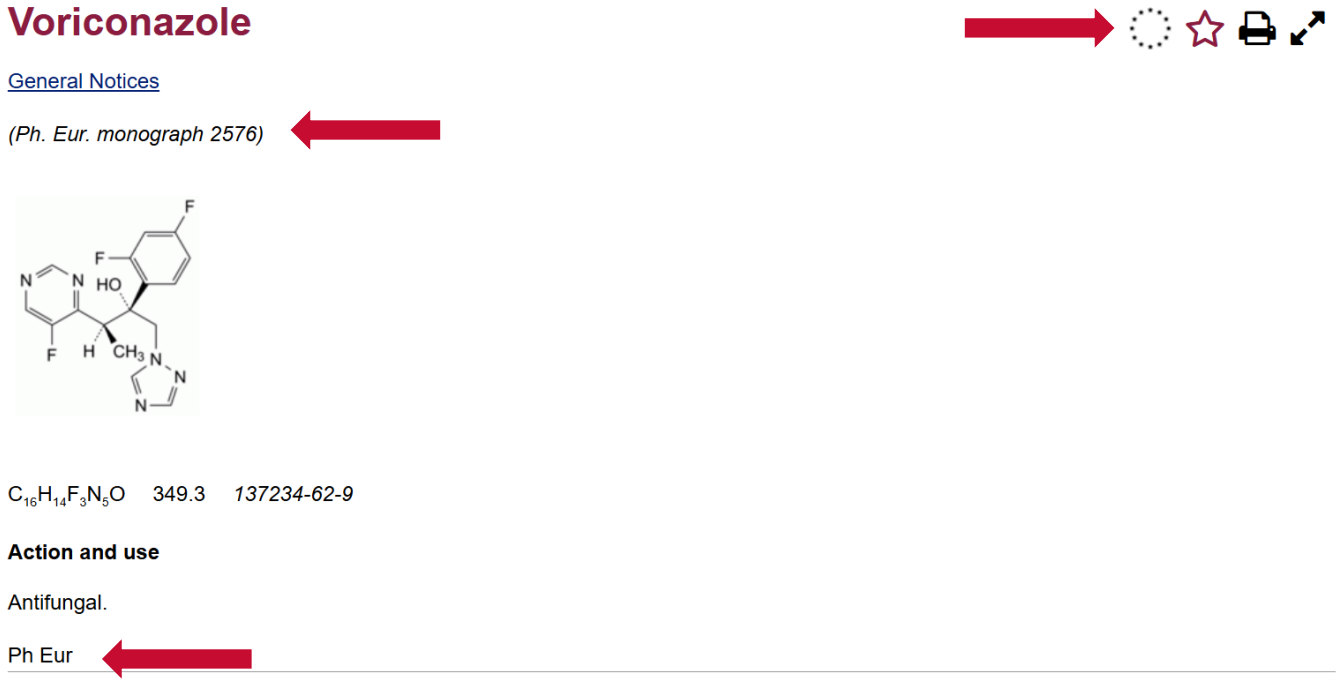
General Notices

BP vs Ph. Eur.

"The following general notices apply to the statements made in the monographs of the British Pharmacopoeia other than those reproduced from the European Pharmacopoeia and to the statements made in the Appendices of the British Pharmacopoeia other than when a method, test or other matter described in an appendix is invoked in a monograph reproduced from the European Pharmacopoeia."

- General Notices part II

Before applying any monograph, check whether it is BP or Ph. Eur. — this determines which General Notices apply



If it's a BP monograph, General Notices part II applies.

If it's a Ph. Eur. monograph, General Notices part III applies.

General Notices Part II

- **Compliance** – Establishes the mandatory requirements for demonstrating compliance with BP standards.
- **Applying the BP** – Explains how General Notices, monographs and appendices should be used together.
- **Consistent Interpretation** – Defines terminology and interpretation rules to ensure uniform application of BP requirements.
- **Flexibility** – Permits validated alternative methods where equivalence to the official BP procedure can be demonstrated.

Can I use an alternative method to the BP method?

"The analyst is not precluded from employing alternative methods, including methods of micro-analysis, in any assay or test if it is known that the method used will give a result of equivalent accuracy. Local reference materials may be used for routine analysis, provided that these are calibrated against the official reference materials. In the event of doubt or dispute, the methods of analysis, the reference materials and the reference spectra of the Pharmacopoeia are alone authoritative."

What this means in practice

You can:

- ✓ Use alternative analytical methods
- ✓ Use local reference materials

However, you must demonstrate:

- ➢ **Equivalent accuracy** to the BP method
- ➢ Comparable Specificity, Precision, Sensitivity as per ICH Q2(R2) – validation of analytical procedures
- ➢ Agreement with the relevant competent authority

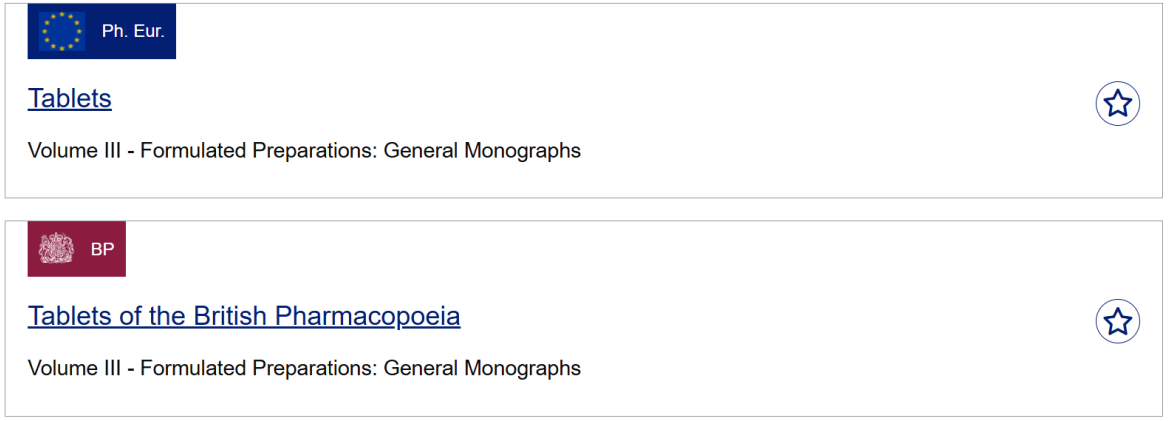
Formulated Preparations: General Monographs

What are general monographs for?

- Apply to **entire dosage form** classes (e.g. Tablets, Parenteral preparations, Oral liquids)
- Define **baseline quality requirements** for Production, Performance (e.g. dissolution, uniformity) and Testing expectations

How they fit into the BP framework

- Must be applied in addition to the individual product monograph
- Provide requirements that are:
  - Not always repeated in the product monograph
  - Still mandatory for compliance



The BP may contain additional requirements to those listed in the Ph. Eur. General Monograph.

Appendices

BP Appendices – where the detail really sits

The BP contains 25 appendices for human use (Appendix I–XXV) and 3 appendices for veterinary use.

Together they include hundreds of individual sections and test procedures.

What is their role?

- Provide the technical requirements that underpin monographs
- Define:
  - Test procedure (e.g. chromatography, dissolution, sterility)
  - System suitability requirements
  - General laboratory practices and conditions.

How are they used?

- Monographs reference appendices instead of repeating common procedures.
- Requirements become mandatory when cited in a monograph.
- A single appendix may support hundreds of different monographs.

Appendix III Chromatographic Separation Techniques

A very important and highly referenced appendix. Applies to all chromatographic methods referenced in monographs.

Defines the principles and requirements for TLC, GC, HPLC, Size-exclusion chromatography, Capillary electrophoresis and related techniques.

Includes:

- System suitability requirements
- Definitions and how to measure parameters
- Adjustment of chromatographic conditions

Common queries we receive:

- "Is there a peak symmetry requirement in this monograph?"
- "Can I use a different column?"
- "We get better chromatography with a different mobile phase composition, is this compliant with the BP?"

Answers to all of these questions can be found in Appendix III Chromatographic Separation Techniques - British Pharmacopoeia

Answers

Peak symmetry (under system suitability)

“Unless otherwise stated, in a test or assay, the symmetry factor (tailing factor) of the peak used for quantitation is 0.8-1.8.”

Column parameters and flow rate

Stationary phase No change of the identity of the substituent (e.g. no replacement of C18 by C8); the other physico-chemical characteristics of the stationary phase (i.e. chromatographic support, surface modification and extent of chemical modification) must be similar; a change from totally porous particle (TPP) columns to superficially porous particle (SPP) columns is allowed provided the above-mentioned requirements are met.

Column dimensions (particle size, length) The particle size and/or length of the column may be modified provided that the ratio of the column length (*L*) to the particle size (*dp*) remains constant or in the range -25 per cent to + 50 per cent of the prescribed *L/dp* ratio. For the application of particle-size adjustment from totally porous to superficially porous particles, other combinations of *L* and *dp* can be used provided that the plate number (*N*) is within -25 per cent to + 50 per cent relative to the prescribed column.

These changes are acceptable provided the system suitability requirements are fulfilled and the selectivity and elution order of the specified impurities to be controlled are demonstrated to be equivalent.

Column dimensions (internal diameter) the internal diameter of the column may be adjusted, even in the absence of a change in particle size and/or length of the column.

Caution is necessary when the adjustment results in smaller peak volumes, due to a smaller particle size or a smaller internal diameter, a situation that may require adjustments to minimise extra-column band broadening by factors such as instrument connections, detector cell volume and sampling rate, and injection volume.

When the particle size is changed, the flow rate requires adjustment, because smaller-particle columns will require higher linear velocities for the same performance (as measured by reduced plate height). Flow rate is adjusted for changes in column diameter and particle size using the following equation:

Adjustment of chromatographic conditions

“The extent to which the various parameters of a chromatographic test may be adjusted without fundamentally modifying the pharmacopoeial analytical procedures are listed below. Changes other than those indicated require revalidation of the procedure.”

Mobile phase

Composition The amount of the minor solvent components may be adjusted by ± 30 per cent relative (see example under Thin-layer chromatography); no component is altered by more than 10 per cent absolute. A minor component comprises less than (100/*n*) per cent, *n* being the total number of components of the mobile phase.

pH of the aqueous component of the mobile phase ± 0.2 pH units, unless otherwise prescribed.

Concentration of salts in the buffer component of a mobile phase ± 10 per cent.

Flow rate In the absence of a change in column dimensions, an adjustment of the flow rate by ± 50 per cent is permitted.

Supplementary chapters

Supplementary Chapters –
Supporting interpretation and application

A series of 10 chapters (I–X) that provide additional scientific guidance and background information.

Cover topics such as: Impurities, Dissolution, Validation, Labelling, Unlicensed medicines, Biological products.

What is their role?

- **Scientific Context** – Explains the principles behind BP requirements and standards.
- **Supporting Guidance** – Aids interpretation and application of pharmacopoeial requirements.
- **Technical Insight** – Provides background on analytical methods, validation and quality control.
- **Best Practice** – Shares scientific rationale and regulatory considerations beyond monograph requirements.

The supplementary chapters are **non-mandatory.** They are informative and guidance based and are closely aligned with BP policy, Ph. Eur Concepts, ICH guidelines.

Useful SCs:

- SC I A. Control of Impurities
- SC VI A. Pharmacopoeial Calculations
- SC III Pharmacopoeial Organisation
- SC V Unlicensed Medicines

BP COMPLIANCE STRUCTURE

Multiple layers work together to ensure complete compliance

Provide the fundamental rules for interpreting and applying the BP. Apply to all monographs and appendices, even when not explicitly referenced.

Apply to dosage form classes (e.g. tablets, parenteral preparations). Define baseline requirements for manufacture, performance and testing.

Set the specific standards for the individual product or substance, including limits, tests and characteristics.

Provide detailed analytical methods, calculations, system suitability requirements and general laboratory procedures.

Offer scientific rationale, best practice and additional guidance to help interpret and apply requirements.

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Thank you

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British Pharmacopoeia 2027

Why it matters and what's new?

Michael Whaley

Head of BP and Labs Team 2

July 2026

Why it matters and what's new

- Key dates and legal basis of the BP 2027
- BP 2027 a year in numbers
- New monographs in the BP 2027
- Revised material in the BP 2027
- New BPCRS
- New guidance
- New online features

Key dates and legal basis of the BP 2027

- British Pharmacopoeia Commission (BPC) endorsed the publication of the BP 2027 and BAN 2027 at the March 2026 meeting in accordance with the UK Human Medicines Regulations 2012

- Official standards for UK pharmaceutical substances and medicinal products
- BP is part of the Medicines and Healthcare product Regulatory Agency
- MHRA Assessors are experts on the BP's Expert Advisory Groups

- BP 2027 published on 1 August 2026
  - Available Digitally (Including Ph. Eur. 13.1) and in Print
  - All formats contain all BP material including over 1500 monographs for Formulated Preparations
  - Digital products benefit from in-year updates available for Ph. Eur 13.2, 13.3 and 14.1
- BP 2027 becomes effective on 1 January 2027

BP 2027: A Year in numbers

18 New Monographs

132 Updated Texts

33 new BANs

118,342 Active Users of BP Online

59 draft text consultations completed

219 BP Experts

11 Observers at the June 2026 BPC meeting

1540 Queries answered

New Monographs

Brimonidine Eye Drops

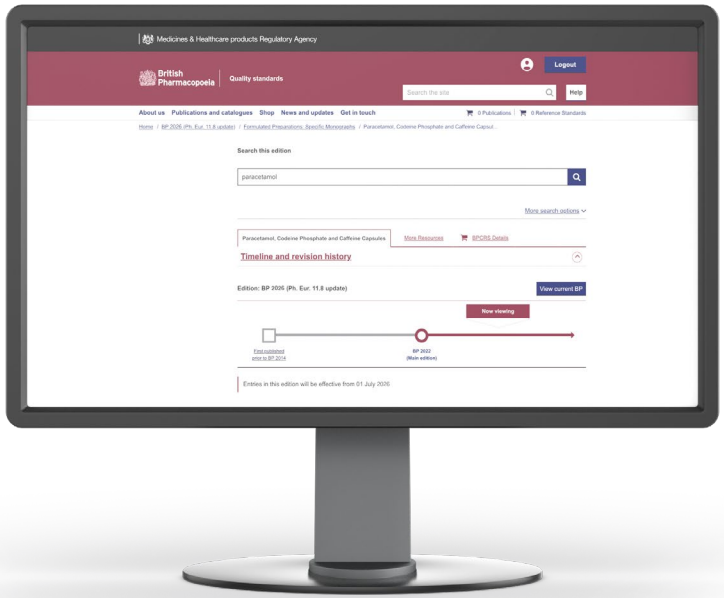
Carvedilol Oral Suspension

Co-Careldopa Prolonged-release Tablets

Copper Sulfate Sterile Concentrate

Fludarabine for Injection
Fludarabine Sterile Concentrate
Fludarabine Tablets

Gliclazide Oral Suspension



Melatonin Oral Solution
Melatonin Prolonged-release Tablets
Melatonin Tablets

Ropinirole Prolonged-release Tablets
Ropinirole Tablets

Topiramate Tablets

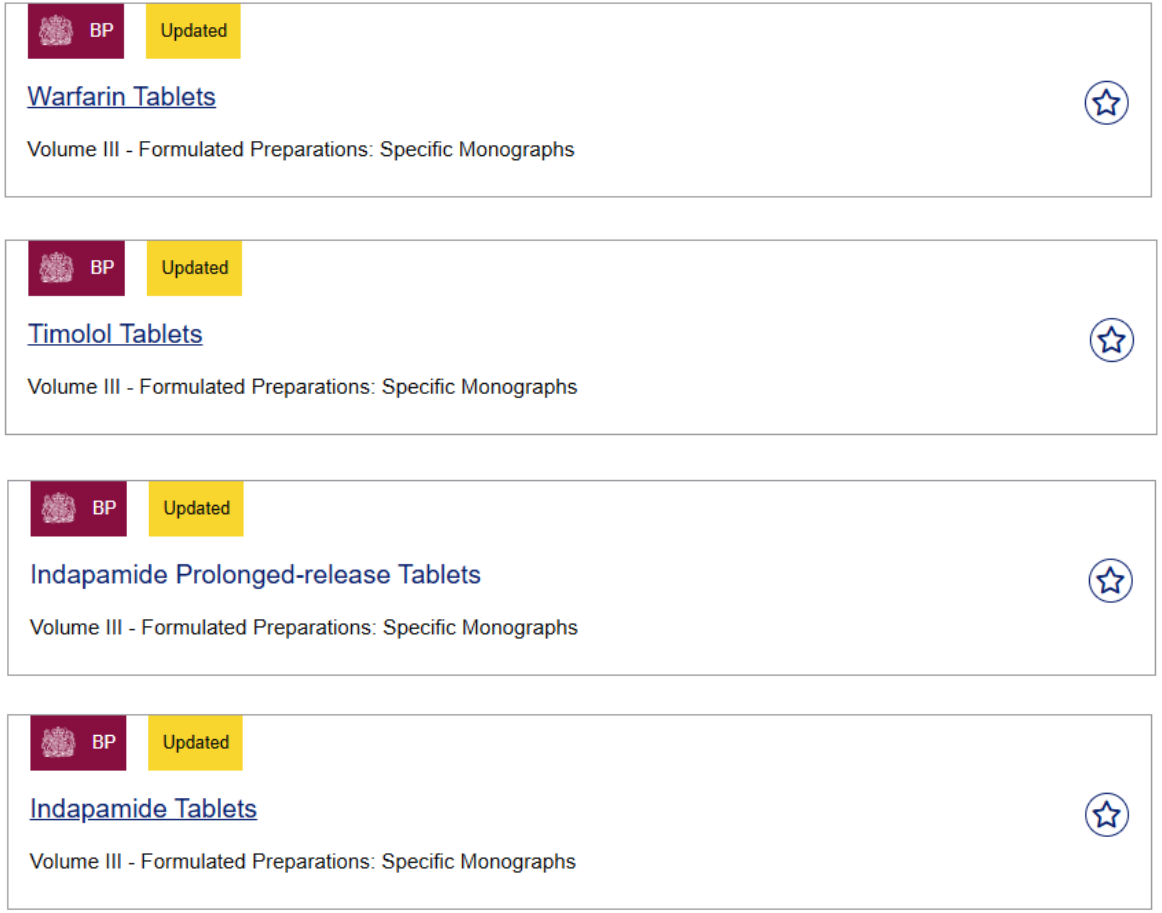
Juniper Tincture

Marbofloxacin for Injection
Marbofloxacin Injection
Marbofloxacin Tablets

Revised Monographs

Over 100 Revised Monographs including technical revisions to:

- Warfarin Tablets
- Timolol Tablets
- Clarithromycin preparations
- Indapamide Prolonged-release Tablets
- Indapamide Tablets



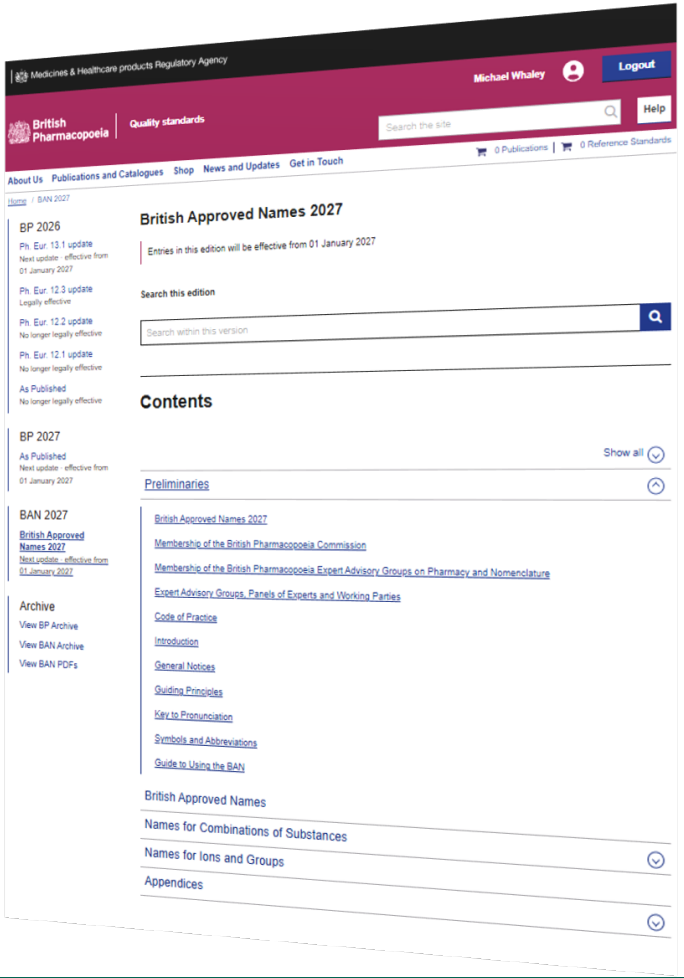
New BPCRS for BP 2027

13 new BP chemical reference substances are being established this year to support the BP 2027.

New
British Approved Names 2027

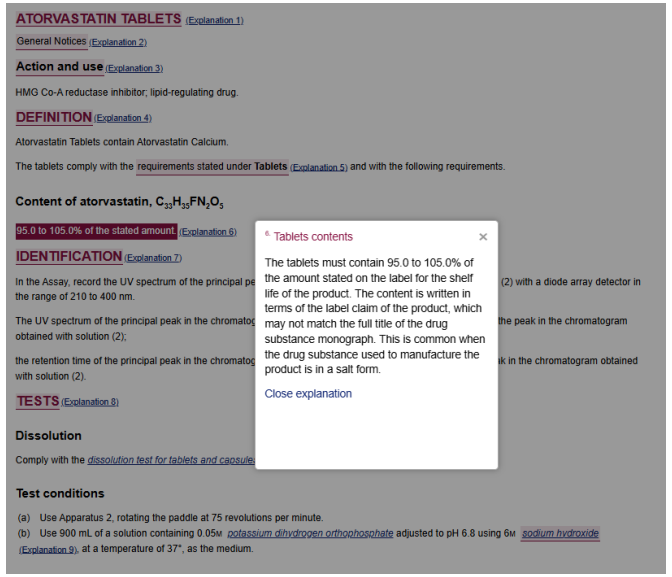
The BAN 2027 digital only publication is available from 1 August 2026.

Thirty-three new entries in this edition including a number of new BANs for veterinary drug names.

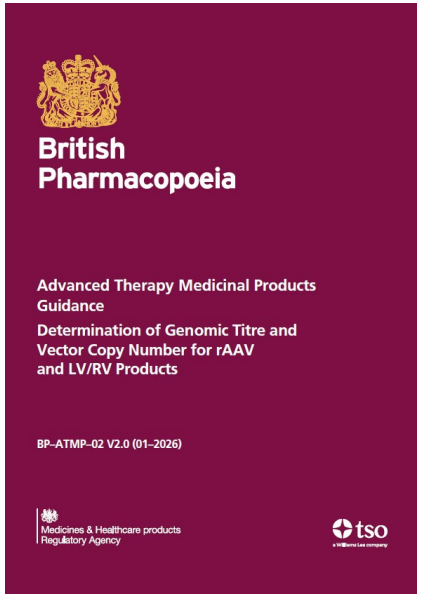


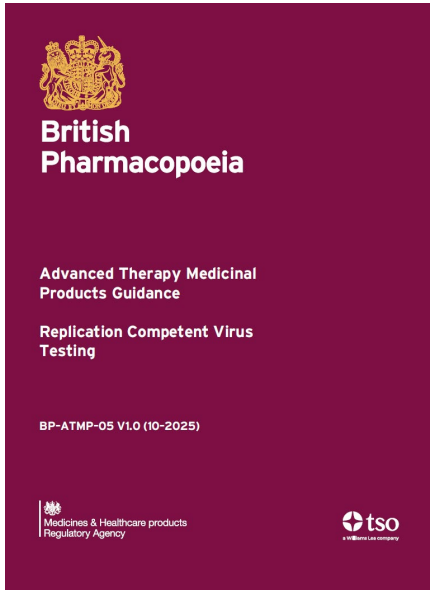
New Guidance

Interactive ‘How to Use the BP’ Guide



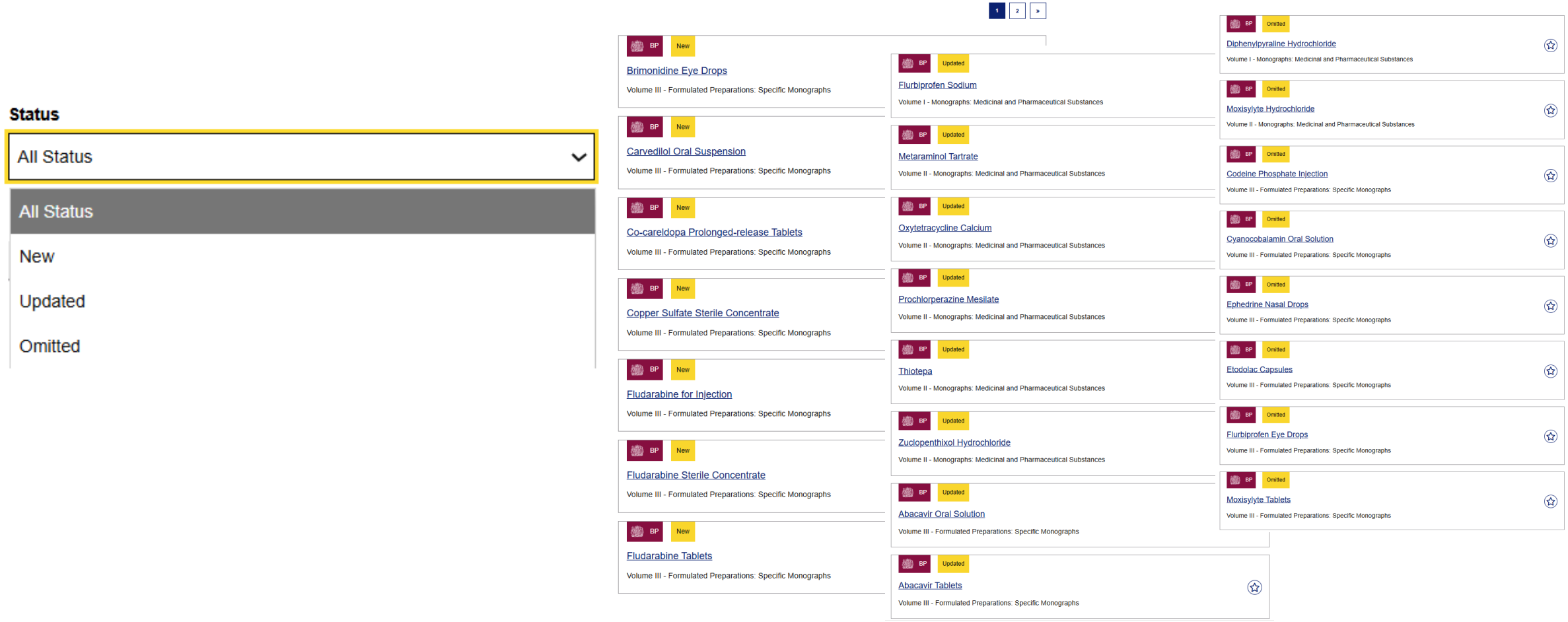
Non-mandatory ATMP guidance





New Online Features

Launching with the BP 2027 is a new way to see which texts are new, updated and omitted.



Worked Example – Co-careldopa Tablets

BP Updated

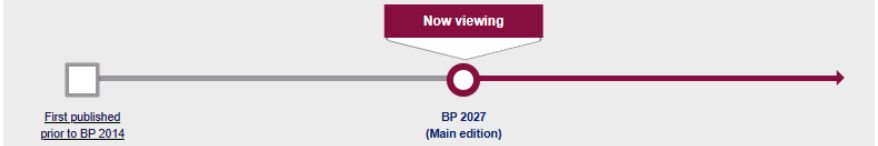
Co-careldopa Tablets

Volume III - Formulated Preparations: Specific Monographs

Co-careldopa Tablets | BPCRS Details

Timeline and revision history

Edition: BP 2027 (As Published) View current BP



Show revision history

The Revision History shows a description of significant amendments made to the monograph.

- **T:** Indicates a technical revision
- **E:** Indicates an editorial revision

BP 2027

- **T:** Production - New requirement added.
- **T:** Content of anhydrous carbidopa $C_{10}H_{14}N_2O_4$ - Revision of content limits to align with regulatory expectations.
- **T:** Identification - Test series replaced with improved methodology.
- **T:** Dissolution - Updated to use (Q) value for acceptance in line with ICH requirements. Chromatographic conditions aligned with new Related substances procedure.
- **T:** Related substances - Test added.
- **T:** Assay - Updated to align with new Related substances procedure.
- **T:** Impurities - Statement added.

Co-careldopa Tablets

General Notices

Levodopa and Carbidopa Tablets

Action and use

Dopa decarboxylase inhibitor + dopamine precursor; treatment of Parkinson's disease.

DEFINITION

Co-careldopa Tablets contain Carbidopa and Levodopa.

The tablets comply with the requirements stated under Tablets and with the following requirements.

PRODUCTION

A suitable test is carried out to demonstrate that the content of hydrazine is not more than 200 ppm of the content of Carbidopa.

Content of anhydrous carbidopa, $C_{10}H_{14}N_2O_4$

~~90.0 to 110.0~~ 95.0 to 105.0% of the stated amount.

Content of levodopa, $C_9H_{11}NO_4$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

In the Assay, record the UV spectra of the principal peaks in the chromatograms obtained with solutions (1), (2) and (3) with a diode array detector in the range of 190 to 400 nm.

The UV spectra of the peaks corresponding to carbidopa and levodopa in the chromatogram obtained with solutions (1) and (2) are concordant to those of the respective peaks obtained with solution (3);

~~A. In the Assay,~~ the retention time of the peaks corresponding to carbidopa and levodopa in the chromatogram obtained with ~~solution~~ solutions (1) ~~exhibits two peaks with the same retention times as those due to carbidopa and levodopa in the chromatogram~~ and (2) are similar to those of the respective peaks obtained with solution (~~2~~ 3).

~~B. To a quantity of the powdered tablets containing the equivalent of 1 mg of anhydrous carbidopa add 5 mL of 0.05M *sulfuric acid*, shake for 2 minutes and filter. Add 5 mL of *dimethylaminobenzaldehyde reagent* to the filtrate. A yellow colour is produced.~~

~~C. To a quantity of the powdered tablets containing 50 mg of Levodopa add 4 mL of *ethanol (96%)* and 1 mL of 1M *sulfuric acid* and shake for 2 minutes. Add 2 mL of *cinnamaldehyde*, allow to stand for 20 minutes, add 50 mL of 0.1M *hydrochloric acid*, shake for 2 minutes and allow to stand. Filter the aqueous layer obtained and to 5 mL add 0.1 mL of *iron(III) chloride solution R1*. To half of the solution add an excess of 5M *ammonia*; a purple colour is produced. To the remainder add an excess of 2M *sodium hydroxide*; a deep red colour is produced.~~

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Thank you

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The British Pharmacopoeia:

An Inspector's Perspective

Samuel Huff Guelbert
GMDP Inspector, Compliance Team 2

July 2026

Brief Introduction

Medicines and Healthcare products Regulatory Agency (MHRA):

- We operate in a statutory framework set by HM Government, working within government and the wider health system to direct overall policy in our regulatory field.

GMDP Inspector in Compliance Team 2:

- Conduct regular inspections of licenced facilities to ensure compliance with Good Manufacturing Practice (GMP).

Me:

- ~ 10 years in sterile pharmaceutical manufacture.
- Joined the agency as an inspector in May 2025.

Overview

- Where does the BP fit into the UK’s regulatory framework?
- How do Inspectors use the BP during an inspection?
- What are the inspectors' expectations for use and implementation?
- Managing updates
- Risks and takeaways

Where does the BP fit into the UK's regulatory framework?

- The Human Medicines Regulations 2012, regulation 371, requires the British Pharmacopoeia Commission (BPC) to prepare and publish new editions of the BP as the **UK standard for medicinal products**.

- The HMRs also require pharmacopoeial compliance throughout the product lifecycle.

- Guidance requires compendial compliance, e.g.
  - A1 6.13 (WFI) / 6.7 (water systems)
  - Ch6 6.20 (Reference standards)

- Harmonised with Ph. Eur.

Appendix XIV C. Test for Bacterial *Endotoxins*

(Bacterial Endotoxins, Ph. Eur. method 2.6.14)[1]

How do Inspectors use the BP during an inspection?

Verify organisational compliance:

- General Monographs:
  - General Monograph for Unlicensed Medicines
  - General Monograph for Capsules

- Specific test methods:
  - Sterility testing (Appendix XVI A)
  - Endotoxin testing (Appendix XIV C)

- General reagents:
  - WFI
  - Acetone

Be able to demonstrate evidence of alignment with the BP during an inspection

Can deficiencies be raised against the BP?

There was no documented check on the resazurin dye level in the fluid thioglycolate media used for sterility testing at the start and end of the test.

C4.26, British Pharmacopoeia Appendix XVI A. Test for Sterility

The QC visual inspection of vials method described in [SOP] was deficient in that: It did not verify adequate intensity of illumination at the viewing point was maintained.

A1.8.31, British Pharmacopoeia Appendix XIII B. Particulate Contamination: Visible Particles

There were inadequate controls to ensure that microbiological samples would always be prepared in a homogeneous and consistent manner to ensure that the results obtained were a true reflection of the batches under test.

C4.26 – Raised as part of a Critical deficiency relating to non-sterile Micro testing

What are the inspectors' expectations for use and implementation?

- The most up to date version is to be used. (BP 2026 – Ph. Eur. 12.3 update)
- Easily accessible by all relevant staff
- Where alternative methods are used, these must be well justified, and risk assessed
- MAH is required to ensure that material and product specifications registered in the MA include tests according to the current pharmacopoeia

Managing Updates

- Perform an annual review:
  - Subscribe to update emails.
  - Updates are well publicised.
  - New versions are published in August for the following year and digitally updated three times in-year with the latest Ph. Eur. Issues.
  - Perform a gap analysis against current written procedures such as reagent preparation and test methods.

- If using the print version, ensure the most recent publication is easily available, archive out of date and superseded copies to avoid mix ups. **Treat it as a controlled document.**

- If using the digital service, ensure **all** relevant personnel have their **own** access.

Risks and Takeaways

- Risks:
  - Narrow review: an individual monograph may not have changed, but its dependencies may e.g.:

    Specific Monograph for Ramipril Capsules:
    - Appendix XII B. Dissolution
    - Appendix III D. Liquid Chromatography
    - Various General Reagents

  - Poor version control of, or accessibility to, the most recent version.

  - Unassessed departure from compendial methods.

- Takeaways:
  - Ensure the BP remains controlled and up to date, including gap assessment against processes.
  - It must be accessible to those whose work relies upon it.
  - Departure from the BP must be justified and risk assessed.

Medicines & Healthcare products Regulatory Agency

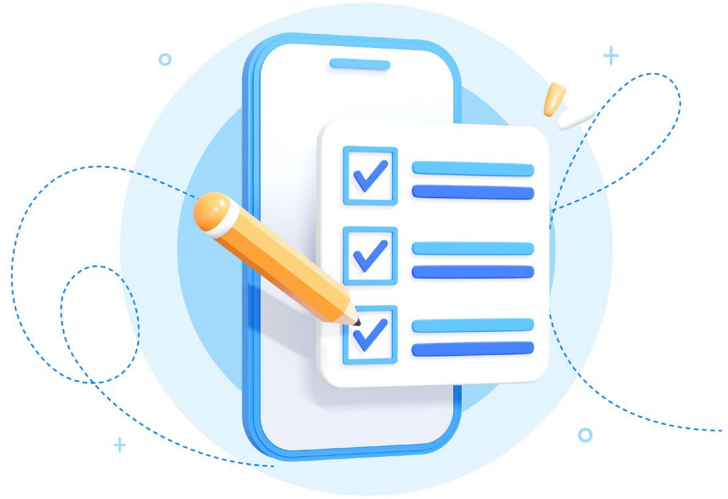
Thank you

Questions and answers

bpcom@mhra.gov.uk

Help shape the future of the British Pharmacopoeia

We value the views of our customers, stakeholders and partners in shaping our activities. We strive to deliver the best possible service and ensure that our products are relevant, user-friendly, and cost-effective. This is why we conduct regular user research to support the development of the BP.



All participants will be entered into a **prize draw for a chance to win £100.**

https://data.bayesprice.com/s3/BP-Survey-2026?samp=6

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