Release Notes

ImpurityPilot™ Software   Beta Version

Qualitative Review Software
Version 1.0 (Beta version)

The ImpurityPilot™ 1.0 software (Beta version) is a qualitative software tool for the identification, confirmation, and structure elucidation of small molecule drug-related degradation products, process-related impurities and byproducts, and excipients in a drug substance and drug product.

Features

- The ImpurityPilot™ 1.0 software (Beta version) aids in impurity profiling, forced degradation studies, and stability studies performed only on the accurate and high resolution AB SCIEX TripleTOF® system.

- The software has a correlation module for batch-to-batch comparison of both analog and MS data, which enables it to correlate analog data, such as UV, DAD, and VWD data, with MS data for impurities identification and confirmation.

- The software has an automated formula finding feature with an integrated structure elucidation tool.

- The software provides access to the ChemSpider Service through the **Results > Interpretation > Prepare > Options > Dictionaries** option, which can be used for identifying unknown impurities.

- Users can populate the main window with all of the predicted structures for a selected potential impurity through the **Results > Interpretation > Prepare > Compound Details > Select** option.

- Users can navigate through all of the shown predicted structures using **>>** and **<<** in the structure pane of the main window.

Where to Get Help

- support@absciex.com
- www.absciex.com

Requirements

- An English (US) version of the Microsoft Windows XP operating system with SP3 or the Microsoft Windows 7 (32-bit or 64-bit) operating system with SP1 is required.

- For computers configured with the Windows 7 operating system, the Microsoft Visual C++ 2010 x86 Redistributable software is required.

- The user must be logged on to the computer as a user with Administrator privileges to install the software.

- A beta license file is required to activate the ImpurityPilot 1.0 software (Beta version). Refer to Activation on page 2.

- Microsoft Word 2007 or later is required to create reports.

Supported Processing Computer

- Dell OptiPlex 9010, or a later model provided by AB SCIEX, is the recommended computer model.

Install the Software

1. Log on to the computer as a user with Administrator privileges.
2. Download the **ImpurityPilot1.0 Beta.exe** file from the Web site.
3. After the executable is downloaded, double-click **ImpurityPilot 1.0 Beta.exe**.
4. On the WinZip Self-Extractor dialog, click **Unzip**.

   The files in the executable are extracted to **C:\ImpurityPilot 1.0 Beta**.
5. After the extraction completes, browse to **Start > Control Panel > Programs and Features**.
6. Make sure that the **Microsoft Visual C++ 2010 x86 Redistributable** software is installed in the **Programs and Features list**.
7. Do one of the following:
   - If the software is not installed, then continue with step 8.
   - If the software is installed, then continue with step 11.
8. Browse to **C:\ImpurityPilot 1.0 Beta\Packages\vcredist\2010\vcredist_x86**.
9. Double-click the **vcredist_x86.exe** file.
10. Follow the on-screen instructions.
11. Browse to **C:\ImpurityPilot 1.0 Beta** and then double-click the **setup.exe** file.
12. Follow the on-screen instructions.

Activation

Note: Before activating the software on a system configured with Windows 7, change the User Account Control (UAC) Settings to prevent issues with installing the license file. Refer to Change the User Account Control (UAC) Settings on page 3.

Tip!: Internet access is required to obtain a license for the software. If the computer where the ImpurityPilot software is being installed does not have Internet access, make a copy of the generated computer ID. On a computer with Internet access, go to http://licensing.absciex.com/activation/ImpurityPilot and then follow the instructions to obtain a license.

1. Double-click the **ImpurityPilot 1.0 Beta** software desktop icon to open the ImpurityPilot software.

   The **ImpurityPilot Software Activation** dialog opens.

2. Type the license key from the license certificate in the appropriate field.

3. Click **Generate Computer ID**.

   This creates a unique identifier for the workstation.

4. Click **Copy ID to Clipboard**.

5. Click the http://licensing.absciex.com/activation/ImpurityPilot link.

6. Follow the instructions to obtain a license.

7. After the required information is submitted, a license file is sent to all of the e-mail addresses provided.

8. Close the browser window.

9. When the e-mail containing the license file is received, copy the license to the workstation desktop.

10. On the **ImpurityPilot Software Activation** dialog, click **Install License File**.

11. On the **Select the new license file to be installed** dialog, browse to and then select the license file.

12. Click **Open**.

    Both the **Select the new license file to be installed** and the **ImpurityPilot Software Activation** dialogs close. The ImpurityPilot 1.0 Beta software opens.

Change the User Account Control (UAC) Settings

1. Click **Start > Control Panel**.

2. Click **User Accounts > Change User Account Control settings**.

3. On the **User Account Control Settings** dialog, move the slider bar to **Never notify me when** and then click **OK**.

4. Continue with Activation on page 2.

Remove the Software

1. Make sure that you are logged on to the computer as a Windows user with Administrator privileges.

2. Make sure that the ImpurityPilot 1.0 Beta software is closed.

3. Click **Start > Control Panel**.

4. Proceed as follows, depending on the operating system:

Windows XP	Windows 7
Double-click **Add or Remove Programs**.	Click **Programs and Features**.
Click **ImpurityPilot 1.0 Beta**.	Click **ImpurityPilot 1.0 Beta**.
Click **Remove**.	Click **Uninstall**.

The license remains on the computer and is automatically used if the software is installed again.

Notes on Use

- A security token is required to access the ChemSpider databases through the Formula Finder option. To obtain a token, complete the registration process at www.chemspider.com/Register.aspx.

Known Issues and Limitations

- The reporting functionality does not support Microsoft Word 2003.

- The Windows 7 operating system may hide the **C:\ProgramData** folder. After installing the ImpurityPilot software on a computer configured with Windows 7, make sure that all users can view and access the **C:\ProgramData\AB Sciex\ ImpurityPilotData** folder.

- Only the neutral formulas from the ChemSpider databases are propagated to the structure pane of the main window. Ion-type formulas are not supported in this version of the software.

- Session files from the MasterView™ software saved with a file type of .XIClist are not supported when searching structures using the **Formula Finder Settings > Dictionaries > Confirm elemental composition in** option in this version of the software.

- If a new **Name** is assigned to one of the potential impurities listed using the **Tools > Assign Ion Types > Assign** option, then the corresponding name in the Results Table is also updated when **OK** is clicked to close the **Assign Ion Types** dialog. Subsequently clicking **Assign ID** might result in an incorrect **Peak ID** being assigned to the potential impurity. To resolve this issue, select the **Tools > Assign Ion Types** option again, and then click **Assign** and **OK** on the **Assign Ion Types** dialog.

- The software only supports high resolution accurate mass data. Data from .wiff files generated using nominal mass instruments, such as the Triple Quad™ and QTRAP® series of instruments, is not supported.

- The software only supports small molecule drugs. Biologics drugs are not supported.

Revision History

Revision	Reason for Change	Date
A	First release	2013/12/19
B	Revised list of features. Changed Supported Equipment to Supported Processing Computer. Removed "Currently, only Common transformations are available for selection in the Set field of the Transformations dialog." from the list of Known Issues and Limitations. Added additional Known Issues and Limitations.	2014/01/02

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