

Interim Comment Form: Preview and Dialogue

Jessica Simpson, M.P.H.
March 29, 2022



- ▶ The following images are design mock-ups – **NOT the actual form**
- ▶ The final look and feel may be slightly different
- ▶ Please disregard dates and document status – these are examples only, **NOT** actual PF documents
- ▶ This is the first structured comment form for PF. It is designed within current constraints, taking into account as much user feedback as possible.

Updates coming to commenting



Comment form, saving, printing, accessing drafts

- ▶ A new comment form is being implemented
 - CC line
 - Structured
 - Identification of submitter
 - Categories of comments
- ▶ When using the comment form you'll be able to save, print, or submit your comment
- ▶ Comments— saved or submitted— will be accessible from the dashboard

Comment form overview



FORUM COMMENTING OPEN
01-Nov-2021 to 31-Jan-2022

Document Tools

HISTORY CONTENTS SUPPORT

SHOW OLDER VERSIONS

FORUM PF 47(6) 01-Nov-2021 to 31-Jan-2022
Commenting open for -55 more days

Submit Comment

BOOKMARK CREATE ALERT

CROSS-REF EMAIL LINK PRINT PAGE

REFERENCE STANDARDS

Draft/Send Comments

To: *sns@usp.org* Document: *Darunavir Oral Suspension - PF 47(6)*

* Indicates required field.

CC:

Subject:

Who are you submitting these comments on behalf of ? *

Myself
 Organization

Public posting of comments: *

Yes
 No

Disclaimer:

Support for the Proposal: *

Yes

Save Comment Print Send Comment Cancel

Who are comments submitted on behalf of



Draft/Send Comments

Subject:

Who are you submitting these comments on behalf of ? *

Myself

Organization

Organization Type: *

Select

- Select
- Company
- Academic Institution
- Government
- Trade Organization
- Other

Public posting of comments: *

Draft/Send Comments

Subject:

Who are you submitting these comments on behalf of ? *

Myself

Organization

Organization Type: *

Trade Organization

Organization Name:

We want your
feedback on this at the
end

New options for confidentiality and support



FORUM COMMENTING OPEN
01-Nov-2021 to 31-Jan-2022

Document Tools

HISTORY CONTENTS SUPPORT

SHOW OLDER VERSIONS

FORUM PF 47(6) 01-Nov-2021 to 31-Jan-2022
Commenting open for -55 more days

Submit Comment

BOOKMARK CREATE ALERT

CROSS-REF EMAIL LINK PRINT PAGE

REFERENCE STANDARDS

Draft/Send Comments

Public posting of comments: *

Yes
 No

Disclaimer:

Support for the Proposal: *

Yes
 Yes, with changes as outlined in the comments
 No, I/we do not want this proposal to move forward

Comment Type: *

Select

Comment: *

Document feedback...

Save Comment Print Send Comment Cancel

Darunavir proposed

1. The bra

2. The

(SM1: S

Corresp

Add the fo

DEFINITION

Darunavir

IDENTIFICATION

• A. The r

• B. The U

ASSAY

• PROCEDURE

Buffer:

Solution

Solution

Mobile

a new monograph based on validated methods of analysis is

on analyses performed with the Zorbax Rapid Resolution SB-C8

ed with the YMC-Pack Pro C18 brand of column with L1 packing.

and NMT 110.0% of the labeled amount of darunavir (C₂₇H₃₇N₃O₇S).

ard solution, as obtained in the Assay.

rd solution, as obtained in the Assay.

Revisi

Revisi

Time	Solution A	Solution B
------	------------	------------

Main comments



FORUM COMMENTING OPEN
01-Nov-2021 to 31-Jan-2022

Document Tools

HISTORY CONTENTS SUPPORT

SHOW OLDER VERSIONS

FORUM PF 47(6) 01-Nov-2021 to 31-Jan-2022
Commenting open for -55 more days

Submit Comment

BOOKMARK CREATE ALERT CROSS-REF EMAIL LINK PRINT PAGE

MONOGRAPH REFERENCE STANDARDS

Darunavir proposed

1. The bra

2. The The

(SM1: S

Corresp

Add the fo

Dar

DEFINITION Darunavir

IDENTIFICATION

• A. The r

• B. The U

ASSAY

• PROCEDURE

Buffer:

Solution

Solution

Mobile

Draft/Send Comments

Comment Type: *

Select

Select

General Comments

Suggested change(s)

Rationale for change(s)

Impact

Comment Type:

Select

Comment:

Document feedback...

Add Comment

Save Comment Print Send Comment Cancel

We want your feedback on this at the end

and NMT 110.0% of the labeled amount of darunavir ($C_{27}H_{37}N_3O_7S$).

ard solution, as obtained in the Assay.

ard solution, as obtained in the Assay.

Different specifications and attachments



Solution
Solution
Mobile

Different Specifications or Methods:

- I/My organization has FDA approval for this compendial article and the specifications in that approval are outside the range proposal in the monograph
- I/My Organization has a different, validated method we wish to submit for consideration

Attached File(s):

Drag & drop files here
Maximum file size of 10MB

Browse

Save Comment Print Send Comment Cancel

	Solution B (%)
	0
	100
	0
	0

Diluent
Standard

Sample solution: Nominally 0.5 mg/mL of darunavir from the Oral Suspension prepared as follows. Homogenize the Oral Suspension by manual shaking and determine its density. Transfer an accurately weighed quantity of the Oral Suspension, equivalent to about 1.0 g, into a 200-mL volumetric flask. Add 100 mL of Diluent and shake for 30 min. Dilute with Diluent to volume. Pass through a suitable filter of 0.45-um pore size.

Comments on dashboard



usp USP-NF Search for General Chapter, Monograph here! Home Bookmarks Profile

My Dashboard

- ✓ **Currently Official** *USPNF 2021 Issue 3* *Published June 01, 2021*
- ✗ **PF 47(6)** *Commenting closed*
- ☰ **PF 48(1)** *Commenting open for 55 more days* *January 3, 2022 to March 31, 2022*

My Resources

MY VIEWING ACTIVITY BOOKMARKS **COMMENTS**

DATE	PAGE	SECTION	PUBLICATION
04-Feb-2022	Test Solutions	Reagents	Forum USP41-NF36
03-Feb-2022	Isopropyl Alcohol	Monographs	Forum USPNF 2021 Issue 3
01-Feb-2022	(17) Prescription Container Labeling	General Chapters	Forum USPNF 2021 Issue 3

Accessing comments



My Resources

MY VIEWING ACTIVITY BOOKMARKS COMMENTS

DOCUMENT	COMMENTING STATUS	COMMENTING DATE	PUBLICATION	SUBMISSION STATUS	LAST MODIFIED
Bromelain PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Draft	28-Mar-2022
Norflurane PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Draft	28-Mar-2022
Bromelain PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Draft	28-Mar-2022
Polyethylene Glycol 30 Dipolyhydroxystearate 5 PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Submitted	24-Mar-2022
Bromelain PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Draft	24-Mar-2022
〈1604〉 Presentation of Aerodynamic Particle Size Distribution (APSD) Measurement Data for Orally Inhaled Drug Products PF 48(1)	Commenting Open	03-Jan-2022 to 31-Mar-2022	PF 48(1)	Draft	01-Mar-2022
〈1604〉 Data					

Feedback and Q&A



- ▶ What categories did we miss?
 - Critical comments
- ▶ What do you want to see next?

Draft/Send Comments

Subject:

Who are you submitting these comments on behalf of? *

Myself
 Organization

Draft/Send Comments

Organization Type: *

Select
Select
Company
Academic Institution
Government
Trade Organization
Other

Public posting of comments: *

Comment Type: *

Select
Select
General Comments
Suggested change(s)
Rationale for change(s)
Impact

Thank You



The standard of trust