

Confirms to ISO 9187 Standards

ABF20 Series

Ampoule Break Force Tester

Ampoule Break Force Tester is used to determine the force required to separate the ampoule stem from the body and for assessing whether a clean break is obtained.

ISO 9187 specifies the minimum breaking force to be 30N and the maximum breaking force to be 80N, 90N, and 100N for ampoules of <5ml, 10ml and >20ml respectively.

Ampule Break Force Tester

Variable Speed Model with Stepper Drive

Digital Model with Backlit LCD Display for easy readability.
With Peak hold facility.

Motorised operation with Ball screw mechanism for extra smooth operation.

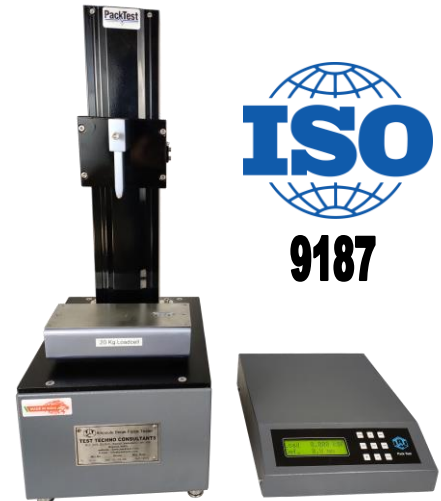
Not dependent on operator skill.

Test Speed : 10 mm/min.

Pre/Post Test Speed : 250mm/min

Model Series : ABF-20

Capacity: 20 Kg with least count of 2 gm.



Ampoule Break Force Tester accessories / fixtures :

- Top Wedge (common for all ampule sizes)
- Acrylic Guard (common for all ampule holders up to 20 ml)
- Ampoule Holder
 - Universal Holder (1-5 ml)
 - Universal Holder (>10 ml)
 - Dedicated Holder (for each ampule size) with auto-centering.

INCLUDED with machine.

INCLUDED with machine.

NOT INCLUDED with machine.

Utilities Required :

- 1) Power Supply (Current : Max 5 Amps) :
 - a. For India (Domestic Model) : 230 Volts A.C., 50 Hz. Clean power.
 - b. For Outside India (Export Model) : As per your country's power rating.
- 2) Calibration weights : 5 Kg (2 + 2 + 1 Kg)
- 3) Desktop PC (Core i3, 4 GB RAM, 500 GB HDD, RS-232 port, 1080p HD Monitor).

DQ/IQ/OQ Documentation is supplied with the equipment.

Software Options : Regular Software / 21-CFR-11 Compliant Software (*Vantage ABF*).



RS-232 Data Cable with USB-Serial Convertor is supplied with all models / SKUs.

Warranty : 12 Months (Ex-Factory)

How to Order ?

Select the Equipment Part Code (SKU) and Optional Test Fixtures and request for a quotation by sending an email to info@packtest.com

Step 1 : Select Part Number / Equipment SKU

Region Options	Industry	-	Equipment	-	Series	-	Software Options
D	P		ABF		ABF20		RS
E							CS

	Options	Description
Type	D	Domestic Model For Sale in India only. Warranty / Support valid only in India
	E	Export Model for Sale outside India only. Comes with a set of emergency spares. International Quality / Warranty / Support.

Industry	P	For use in Pharmaceutical Industry. DQ/IQ/OQ documents are provided with machine.
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Equipment - Series	ABF-ABF20	Ampoule Break Force Tester – 20 Kgf (~200 N) Capacity.
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Software	RS	Regular software. (Not 21-CFR-11 compliant)
	CS	21-CFR-11 compliant software (<i>Vantage ABF</i>) required.

Examples and comparison of Part Code / SKU



Part Code / SKU	Type		Validation Documents	Software	
	Domestic Model	Export Model	DQ/IQ/OQ Documents Provided	Regular Software	21-CFR-11 Compliant Software (<i>Vantage ABF</i>)
DP-ABF-ABF20-RS	✓		✓	✓	
DP-ABF-ABF20-CS	✓		✓		✓
EP-ABF-ABF20-RS		✓	✓	✓	
EP-ABF-ABF20-CS		✓	✓		✓

Step 2 : Select Test Fixtures

Below Fixtures are INCLUDED in the machine by default.

Sr	Item Name	Description
1	Top Wedge	Common for all ampoule sizes.
2	Acrylic Guard	Common for 1-20 ml ampoules. Note : If your ampoule size is >20 ml, you will need to order special Acrylic Guard for 20 ml ampoule, at an additional cost.

Below Fixtures need to be selected and ordered with the basic machine.

Sr	Item Name	Description
1	Universal Ampoule Holder	 <p>Adjustable Height Type.</p> <ol style="list-style-type: none">1) Universal Ampoule Holder for 1-5 ml.2) Universal Ampoule Holder for >10 ml.
or		
2	Dedicated Ampoule Holder	 <p>Dedicated Holder for every specific ampoule size. Provided with 1 end dead stop for quick and easy ampoule placement / alignment. Easier to use.</p> <p>Note :</p> <ol style="list-style-type: none">1) Every specific ampoule will need a specific / dedicated adopter.2) This is made as per the stem and body dia of the sample you will provide.3) If you have 2 different volume ampoules with same stem and body dia but different length, it will be considered as 1 holder.4) If you have 2 same volume ampoules but with different stem and body dia, they will be considered as 2 separate holders.

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Manufactured by :

PackTest Machines Inc

K-1, 601/2&3, GIDC Ranoli
Vadodara - 391350 Gujarat. India.

Email : info@packtest.com

Marketed by :

Sr No.	Feature	Regular Software (Not 21-CFR-11 Compliant)	Vantage Software (21-CFR-11 Compliant) 
1	User Login	No Login. Any user can access the software.	<p>Unlimited Users with individually configurable privileges</p> <p>Incorrect Logins are logged. If user enters 3 wrong passwords, user is SUSPENDED and cannot login again even with correct password. Event is logged as Critical. Only an admin (or user with appropriate privileges can Un-Suspend the suspended user.</p> <p>Auto - Logout after 15 mins of inactivity. (Timeout period can be defined)</p> <p>Auto - Shutdown (software) on inactivity. (Auto-Logout will also trigger Auto-Shutdown)</p>
2	User Rights / Privileges	Any user can : 1) Perform Test 2) Search Test 3) Calibrate Machine 4) Configure Software	<p>Software Admin or any user (with Modify user privileges) can create unlimited users with any of following privileges.</p> <ol style="list-style-type: none"> 1) Perform Test 2) Search Test 3) Calibrate Machine 4) View Audit Trail 5) Add / Edit / Delete users (User Management privilege) 6) Configure Software 7) Review and Approve Test / Calibration reports
3	User Levels	NA	<p>Unlimited Users with Unlimited variable privileges. User List (summary or detailed) can be printed.</p>
4	Software Configuration Options	1) Change Header	<ol style="list-style-type: none"> 1) Change Test Folder 2) Change Backup Folder 3) Set Auto Backup On/Off 4) Set Auto Backup Frequency 5) Set Password Expiry On/Off 6) Set Password Expiry Time (Days) 7) Change Header
5	User Password Expiry / Change	NA	<p>Upon user first login, user has to change password immediately.</p> <p>User can change his/her own password anytime.</p> <p>Users must change password after expiry date.</p> <p>Password expiry time can be defined in software config.</p>

6	Password Complexity	NA	<p>Password should be</p> <ol style="list-style-type: none"> 1) 8-20 characters long 2) Has to contain alphabets, numbers and &#%\$@. 3) Password should contain atleast 1 uppercase, 1 lower case and 1 special character 4) New password cannot be same as previous 3 passwords.
7	User Addition / Deletion	NA	<p>User can be added or deleted by Software Admin or anyone who has User Management privilege. User cannot delete himself. No one can delete the SUPER USER.</p>
8	User Suspension	NA	<p>User can be suspended/un-suspended by Software Admin or anyone who has User Management privilege. Suspended user cannot login to software. If he tries to login, a Critical Audit Trail entry will be passed.</p>
9	Data Storage	NA	<p>Data is stored in an internal database. PDF reports are generated as and when demanded.</p>
10	User Signature	User must type or select his / her name when the software starts.	<p>User's details captured from the login is posted on the report "analysis done by" section.</p>
11	Reviewer Signature	NA	<p>Reviewer can login with his credentials, review and approve Test and Calibration Data. Once approved, the report will carry his E-Sign.</p>
12	Backup Data	NA	<p>If Autobackup is ON, software will automatically backup all configuration files and test data as per frequency chosen in Software Configuration.</p> <p>Note : Backup Location has to be a local drive or a network location mapped as a Local Drive.</p>
13	Audit Trail Data	NA	<p>Software captures important events and logs them in the audit trail log. A PDF report can be generated as and when required. Critical Events will be flagged separately. Audit Trail Report can be pulled for a date range or user or event.</p>

14	Aborted Tests / Calibrations	NA	Aborted Tests and Calibrations are saved. These events are logged in Audit Trail as "Critical".
15	Ignore a Test Value	NA	<p>No test result can be avoided from being reported. But the user can mark a particular result as abnormal.</p> <p>Abnormal results are not considered in statistical calculations but will still be shown in report.</p> <p>User needs to justify the Abnormal values (if any) in the remarks section.</p> <p>A test report can have 10 normal samples + up to 5 abnormal samples.</p> <p>Only normal tests will be used for statistical calculations.</p>
16	Test / Calibration Report Format	Report Format is fixed in software. Not changeable by user.	
17	Report Header	Text Header with 3 lines of Text.	Image Header with Logo or Text Header with 3 lines of Text.
18	Other Features	NA	<p>Incorrect Shut Downs are logged in Audit Trail.</p> <p>Equipment ID is printed on all Test / Calibration / Audit Trail Reports</p> <p>Automatic Pre-Calibration Diagnostics of communication.</p> <p>Option of Pre-Analysis Diagnostics (10-15 seconds) to prevent communication errors.</p> <p>Enhanced data handling and communication with equipment.</p>

