



Prexima, IMA Active's new series of tablet press machines.

Prexima

From design to tablet manufacturing

IMA Active's new series of tablet press machines

IMA Active's experience and expertise in the pharmaceutical industry have been carefully channelled into Prexima, the new series of tablet press machines. Powered by IMA's knowledge of the sector, designed with unique Italian style, built to deliver top-level performance, the Prexima series is the best solution to handle all production volumes.

Stefania Barzanti

IMA Active Marketing Manager

Stefania Barzanti received her degree in Politic Sciences and Sociology at the University of Bologna in 1994. Since 1995 she has been working at IMA Marketing Department. Today she is Marketing Manager for the whole IMA Active Division, the sector dedicated to the design and manufacture of automatic machines for the processing and manufacturing of pharmaceuticals in solid form.

Anastasiya Zakhvatayeva

IMA Active Process Technologist

Anastasiya Zakhvatayeva received her Degree in Chemistry and Pharmaceutical Technology at the University of Bologna in 2013. She is currently employed as specialised technologist at Process Development R&D Laboratory in IMA Active Division. Her work is mainly focused on the optimization of tableting process applied to pharmaceutical and nutraceutical products.

A key feature of Prexima is the complete isolation of the processing area. Based on the proven Comprima concept, Prexima ensures complete separation between processing and mechanical areas thanks to the use of seals and protections designed on purpose. Limited surfaces in contact with the product reduce cleaning times as well as avoid cross contamination. In addition to extending the duration of cams, tooling and compression rollers, the machine lifecycle is longer.

Prexima has also been designed for accessibility to enable straightforward operations, easy inspection and cleaning. The processing area is fully accessible once the external doors are opened. Cam, rollers, and other components in the mechanical area are immediately visible when the side protections in the processing area are removed. Except from maintenance purposes, access to the machine basement is not required for machine set up, changeover, or cleaning operations.

The extraction of the turret is quick and easy thanks to a rotating arm completely housed in the mechanical compartment. The turret can be removed complete with dies and lower punches, thus preventing the powder from falling into the mechanical area through the lower punch bores. The Human Machine Interface (HMI) guides the operator step by step during each phase of turret dismounting.

Positioned in the machine basement, the lubrication system is automated and works with only one type of oil. The lubricant oil does not go into the processing area, hence can be recovered into an apposite container and

recirculated. As a result, the machine is clean and requires less maintenance, with no oil dripping from punches and no black spots on tablets.

The Prexima's compression support is based on robust columns linked together by strong cast iron structures. Upper and lower pre-compression and main compression rollers are housed within this robust frame and fixed on both sides. Both rollers have the same diameter, thus allowing flexible adjustment and optimal performance with a wide range of products. This exceptionally sturdy structure – an essential requisite for the production of quality tablets – guarantees compression forces up to 100 kN with maximum reliability.

To keep noise level to a minimum, Prexima has been fitted with sealing on machine doors, sound-proof panels in the basement and anti-vibration feet. Prexima has been tested at the anechoic chamber at the University of Ferrara (Italy), which has offered IMA recommendations for the choice of the best technical solutions and sound-proof materials. The result is a very quiet machine with minimum vibrations.

Prexima is fitted with the new XIMA HMI, which was awarded the 2015 A' Design Award for its strategic role in improving operators' efficiency. The control system is featuring linearity, intuitiveness, iconicity and scalability. XIMA follows the principle of linear navigation, in that each action of the user on the HMI corresponds to only one control signal. In addition XIMA is based on the principle of natural mapping: the synoptic uses spatial correspondence between the layout of the controls and



Prexima 300 pre/main compression rollers.

the devices being controlled, thus reproducing the main machine workflow. The icons of XIMA serve as perceivable indicators that suggest appropriate functions to the user. The principle of scalability, in the end, enables XIMA to be scaled to multiple devices and multiple machines.

Tests have been a key role in the development of Prexima right from the start. The most difficult-to-manage products have been tested, allowing a timely feedback on the machine design. IMA Active is still performing trials with several formulations: here is one of the most meaningful.

CASE STUDY: ANTIBIOTIC BASED FORMULATION WITH HIGHLY ELASTIC PROPERTIES UNDER COMPRESSION

The study was carried out on a formulation based on amoxicillin trihydrate formulation, which composition is shown in table below.

Amoxicillin trihydrate	87.5%
Microcrystalline cellulose	7.6%
Talc	3.0%
Colloidal silica	0.90%
Magnesium stearate	1.0%

The mean particle size distribution of the blend is around 650 micron, with bulk and tapped density of respectively 0.63 and 0.75 g/cm³. The powder, as results from the Carr Index value of 23, has a good flowability.

Target of the study:

Obtain oblong shape tablets of 17 mm x 7 mm with average weight of 600 mg (API content circa 525 mg) with percent deviation related to the average less than 5%. Such parameters as hardness uniformity, friability and disaggregation time were evaluated as well.

Process parameters:

	u.m.	Value
Turret speed	Rpm	120
Production speed	Tab/h	194,400
Feeder type	profile	Two paddles, flat profile
Feeder speed	Rpm	30
Pre-compression force	kN	15
Main compression force	kN	20 (±6%)
Production yield	%	98.9%

Process description:

The amoxicillin exhibits highly elastic properties that cause variations in hardness value of single tablets. The same diameter of the pre-compression and of the main

compression roller enables to transform the tableting process in two identical compression steps, rather than discriminating between pre-compression and main compression steps.

In this case, the pre-compression force was kept at 15 kN, whereas the main compression was slightly higher, between 18 and 20 kN. This seems to improve the hardness uniformity, as can be seen from the table below. All the other parameters comply with the requirements of European Pharmacopoeia:

Parameter	u.m.	Value
Average weight	mg	603
Weight variation	%	+2.65/-1.82
Average hardness	N	107
Hardness variation	%	+11.21/-8.41
Average thickness	Mm	5.63
Thickness variation	%	+0.71/-1.77
Disaggregation time	min	<5
Friability	%	0.16

