PharmaCote®

Durability,
Productivity,
Longevity.

TSAR PREDICT

I HOLLAND® PHARMACOTE

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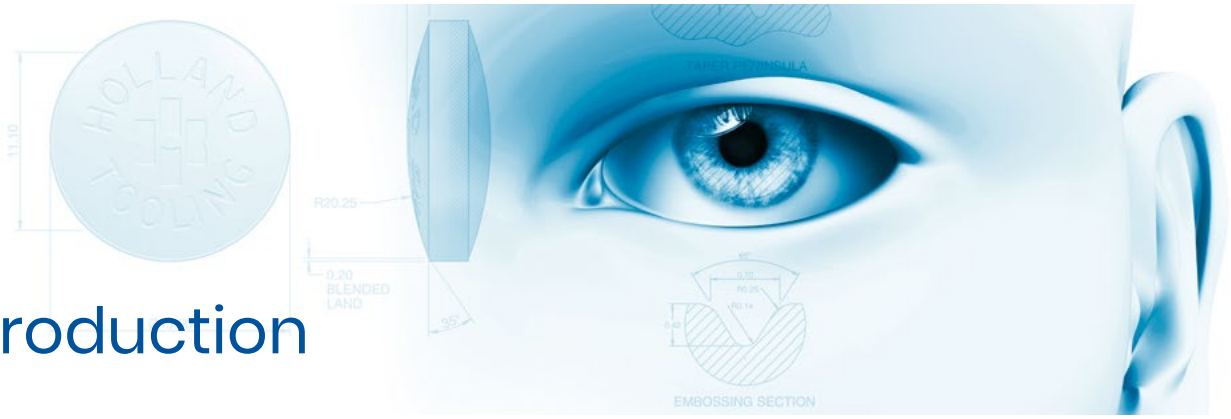


Introduction

As one of the worlds leading tablet tooling manufacturers I Holland has been instrumental in introducing many innovative and unique developments to the industry including the 'Rotating Head', 'Universal Seal Groove', and is author of the industry's leading global tooling standard the Eurostandard.

Since the introduction of PharmaCote® CN in 2007 I Holland has carried out extensive research (both academic and in the field) into anti-stick coating solutions using many forms of advanced technology such as Atomic Force Microscopy (AFM); scanning electron microscopy; laser profilomitry; adhesion mapping; x-ray photoelectron spectroscopy; raman spectroscopy and time of flight secondary-ion mass spectrometry. In addition, work on abrasion resistance is continuing including nano-wear testing to simulate wear caused by abrasive granules on punch tip surfaces.

Our focus is on providing the best customer service possible by furthering tabletting science and developing solutions that help to enhance the performance of our punches and dies, extending product life and increasing yield for our customers. I Holland PharmaCote® products offer solutions for sticking, corrosion, pitting and abrasion.

Due to the many varying parameters in tablet production, including environmental conditions and differences in compounds to be compressed, the performance of these coatings can vary from application to application. As part of I Holland's commitment to customer service our experienced technical staff will offer up to date information and assistance when selecting an appropriate PharmaCote® product for your tooling.

This booklet details the range currently available for application to I Holland tooling. The Research and Development team are constantly working on the development of new solutions.

For further information on our R&D activity please contact: info@iholland.co.uk

TSAR PREDICT

FREE SERVICE
Over 1000 predictions made!

TSAR≈PREDICT Is A Revolutionary Free Service For I Holland Customers

WHAT DOES IT DO?

TSAR≈PREDICT was designed to forecast the correct anti-stick PharmaCote® coating solution for your formulation.

It calculates single particle adhesion to the punch tip face without time consuming and expensive field trials.

WHO IS IT AIMED AT?

Any tablet manufacturer experiencing sticking problems including pharmaceutical, nutraceutical, industrial, confectionery, veterinary applications.

WHAT DOES IT COST?

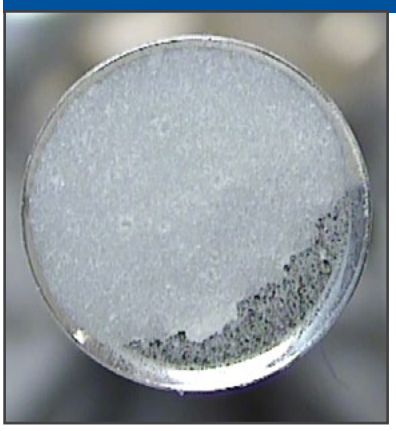
TSAR≈PREDICT is a free of charge service available to all I Holland customers.

WHAT INFORMATION DOES I HOLLAND NEED FROM ME?

All we need from you is the name of the API or main component of the formulation. Even if this API is confidential we can work with basic characteristic information on key physical properties.

ABOUT TSAR

The TSAR≈PREDICT service is the culmination of two years' research in association with the University of Nottingham to investigate the root causes of why formulations stick to tablet tooling surfaces. It takes into account interactions between various parameters such as Van der Waals Forces; capillary action and deformation mechanics. This research has been a key part of I Holland's Tabletting Science Programme.



PHARMACOTE® ANTI-STICK

COATING TECHNOLOGY...
BACKED BY RESEARCH

THE PHARMACOTE® RANGE

PharmaCote® HC (Hard Chromium)

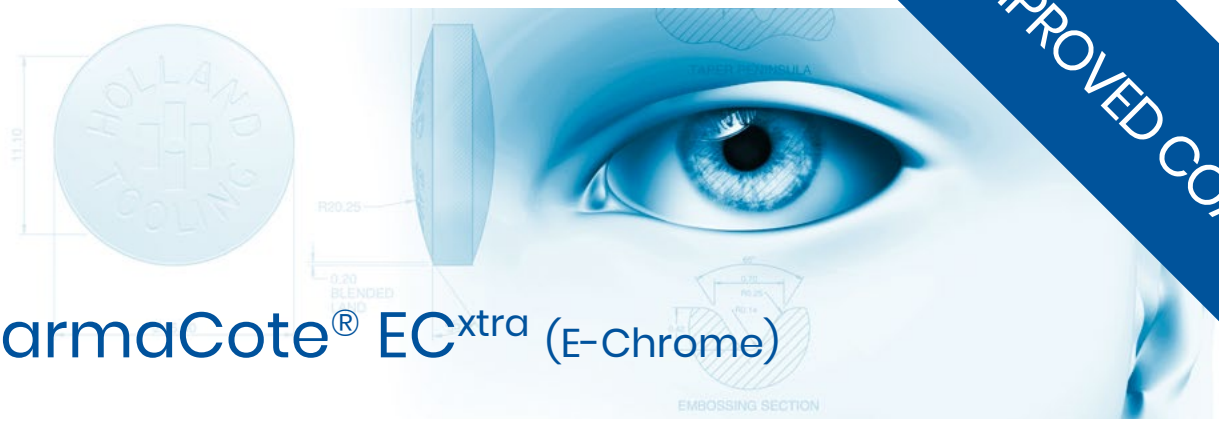
Description	A basic silver coloured coating which protects the surfaces of punches & dies. Enhances corrosion & wear resisting properties. Reduces friction & adhesion.
Features	PharmaCote HC undergoes Hydrogen de-embrittlement to combat the loss of strength associated with traditional hard chromium. Tip Face Thickness: 1-2 microns. Hardness: 900Hv (est.).
Benefits	Increases surface hardness over base material improving wear resistance. Reduces friction & sticking to some extent. Low cost. Provides some general corrosion protection. Extremely easy to clean & maintain using an ultrasonic bath & light automated polishing.
Application	Can be applied to HPG-S, HPG-P & HPG-SS. Can be applied to both punches & dies.

While I Holland always dispose of hard chromium waste products responsibly and within guidelines, the by-products of hard chromium are under review by environmental agencies.

PharmaCote® HC+ (Hard Chromium Plus)

Description	A unique proprietary I Holland process that modifies the coating surface reducing the effect of formulation sticking to the punch face.
Features	Tip Face Thickness: 1-2 microns. Hardness: 900Hv (est.).
Benefits	As for HC, PLUS: Improved anti-stick properties over standard hard chromium. Increased output through further enhanced anti-stick properties reducing tabletting problems.
Application	Can be applied to HPG-S, HPG-P & HPG-SS. Can be applied to both punches & dies.

While I Holland always dispose of hard chromium waste products responsibly and within guidelines, the by-products of hard chromium are under review by environmental agencies.



IMPROVED COATING

PharmaCote® EC^{xtra} (E-Chrome)

Description

A silver grey coating providing improved anti-stick, anti-corrosion & anti-wear properties over traditional hard chromes.

Features

No micro-cracks (as can be found with hard chromium).
Tip Face Thickness: 3-5 microns.
Hardness: 1700Hv (est.).

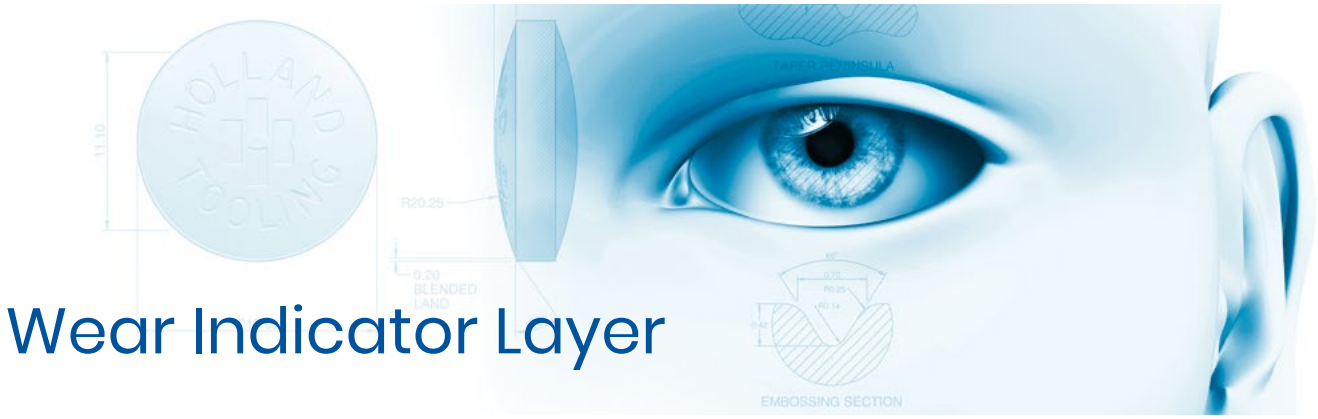
Benefits

Improved corrosion resistance from our previous EC coating & significantly better than standard hard chromium (due to non-porous surface).
More wear resistant than standard hard chromium.
Improve sticking compared to standard hard chromium in many cases.
Stronger punch due to no weakening of the substrate material from hydrogen embrittlement.
A tougher, shock resistant punch provided at lower cost than premium coatings requiring HPG-P substrate material.
Extremely easy to clean and maintain using an ultrasonic bath & light automated polishing.

Application

Applied to HPG-S steel only.
Applied to punches only.


HOLLAND
TOOLING



Wear Indicator Layer

Description	A distinctive gold coloured indicator layer that is revealed as the functional coating nears the end of working life cycle. This can be applied to PharmaCote® CN/CN+/CX/CX+.
Features	Enhances the performance of the CN/CN+/CX/CX+ layer Thickness: 0.5 micron Hardness: 2000Hv (same as the surface layer)

PharmaCote® CN (Chromium Nitride)

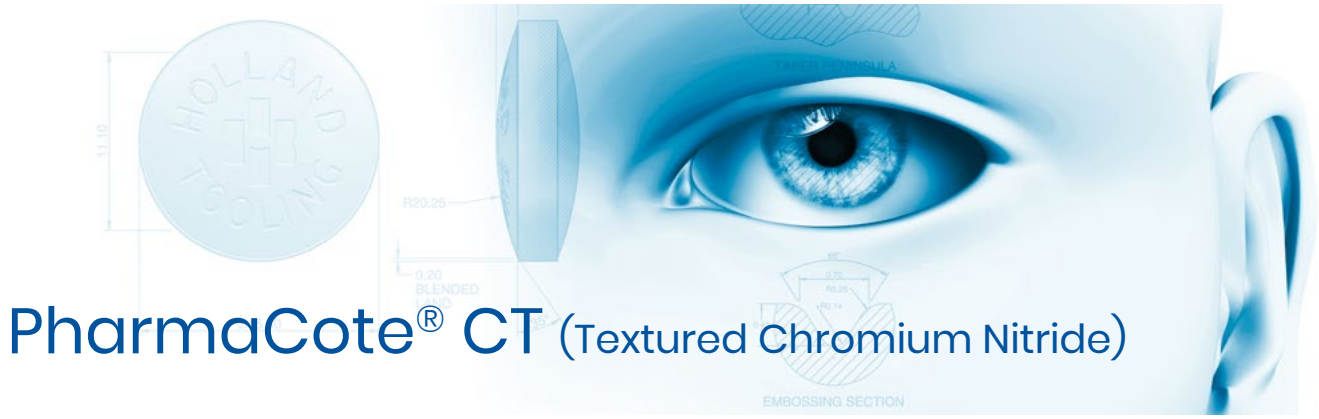
Description	A silver grey coating providing a superior punch surface which is very smooth when compared with many CN coatings due to our unique method of application. All round best performing anti-stick coating.
Features	Extremely smooth coating. Tip Face Thickness: 2-4 microns. Hardness: 2000 Hv (est).
Benefits	Excellent anti-stick properties. Superb corrosion resistance up to 9X the corrosion resistance of standard hard chromium. Good wear resistance more than 2X the hardness of standard hard chromium. Extremely easy to clean and maintain using an ultrasonic bath and light automated polishing.
Application	Applied to HPG-P & HPG-SS Steel. Applied to both punches and dies (NOTE: all over coating supplied as standard, tip & barrel option available to optimise wear characteristics of HPG-P steel on the compression rollers).

Note: PharmaCote® CN is compatible with the wear indicator layer for added assurance when the coating is reaching the end of its life cycle.

PharmaCote® CN+ (Chromium Nitride Plus)

Description	An additional surface modification with anti-stick properties at low additional cost. This further reduces the effect of formulation sticking to the punch face.
Features	Extremely smooth coating. Tip Face Thickness: 2-4 microns. Hardness: 2000 Hv (est).
Benefits	As for CN, PLUS: Further enhanced anti-stick properties reducing tabletting problems. Offers a proven alternative to magnesium stearate spray system without reducing product yield. Extremely easy to clean & maintain using an ultrasonic bath & light automated polishing.
Application	Applied to HPG-P & HPG-SS Steel. Applied to both punches and dies (NOTE: all over coating supplied as standard, tip & barrel option available to optimise wear characteristics of HPG-P steel on the compression rollers).

Note: PharmaCote® CN+ is compatible with the wear indicator layer for added assurance when the coating is reaching the end of its life cycle.



PharmaCote® CT (Textured Chromium Nitride)

Description

I Holland's exclusive (Patent Protected) surface treatment in combination with our unique PharmaCote® CN coating generates a superb anti-stick tip face for tablet production.

Features

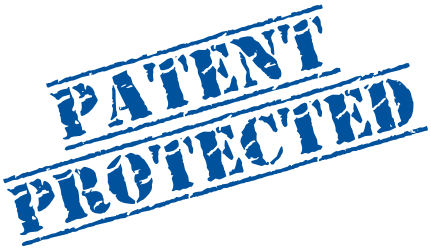
Silver Matt Finish Tip.
Tip Face Thickness: 2-4 microns.
Hardness: 2000 Hv (est).

Benefits

Superior anti-stick properties.
Good corrosion resistance.
Good wear resistance more than 2X the hardness of standard hard chromium.
Extremely easy to clean & maintain using an ultrasonic bath & light automated polishing.
Produces a unique satin finish tablet.

Application

Applied to HPG-P steel only.
Textured surface treatment applied to punch tip faces only. Remainder of the punch is CN coated as standard (Tip & barrel option available to optimise wear characteristics of HPG-P steel on the compression rollers).



PharmaCote® CX (Chromium Nitride Extra)

Description	An enhanced Chromium Nitride, silver grey coating that is very smooth due to our unique method of application. In addition to all the benefits of PharmaCote® CN, PharmaCote® CX offers prolonged tooling life.
Features	Extremely smooth coating. Tip Face Thickness: 6-8 microns. Hardness: 2000 Hv (est).
Benefits	Prolonged tooling life due to thicker coating application Excellent anti-stick properties. Superb corrosion resistance up to 13 X the corrosion resistance of standard hard chromium. Good wear resistance, more than 2 x the hardness of standard hard chromium. Extremely easy to clean and maintain using an ultrasonic bath and light automated polishing.
Application	Applied to HPG-P and HPG-SS Steel. Applied to punches only (NOTE: all over coating supplied as standard, tip & barrel option available to optimise wear characteristics of HPG-P steel on the compression rollers).

Note: PharmaCote® CX is compatible with the wear indicator layer for added assurance when the coating is reaching the end of its life cycle.

PharmaCote® CX+ (Chromium Nitride Extra Plus)

Description	An additional surface modification with anti-stick properties at low additional cost. This further reduces the effect of formulation sticking to the punch face.
Features	Extremely smooth coating. Tip Face Thickness: 6-8 microns. Hardness: 2000 Hv (est).
Benefits	As for CX, PLUS: Further enhanced anti-stick properties reducing tabletting problems. Offers a proven alternative to magnesium stearate spray system without reducing product yield. Extremely easy to clean & maintain using an ultrasonic bath & light automated polishing.
Application	Applied to HPG-P and HPG-SS Steel. Applied to punches only (NOTE: all over coating supplied as standard, tip & barrel option available to optimise wear characteristics of HPG-P steel on the compression rollers).

Note: PharmaCote® CX+ is compatible with the wear indicator layer for added assurance when the coating is reaching the end of its life cycle.

PharmaCote® TN (Titanium Nitride)

Description

A thin, gold coloured coating applied to the surfaces of both punches & dies which can improve wear resistance.

Features

Low thermal conductivity.
Tip Face Thickness: 2-4 microns.
Hardness: 2300 Hv (est.).

Benefits

A very hard surface layer that can improve wear resistance.
Resistance to heat transfer during compression.
The gold colour can be used for easy identification of tooling sets.
Extremely easy to clean & maintain using an ultrasonic bath & light automated polishing.

Application

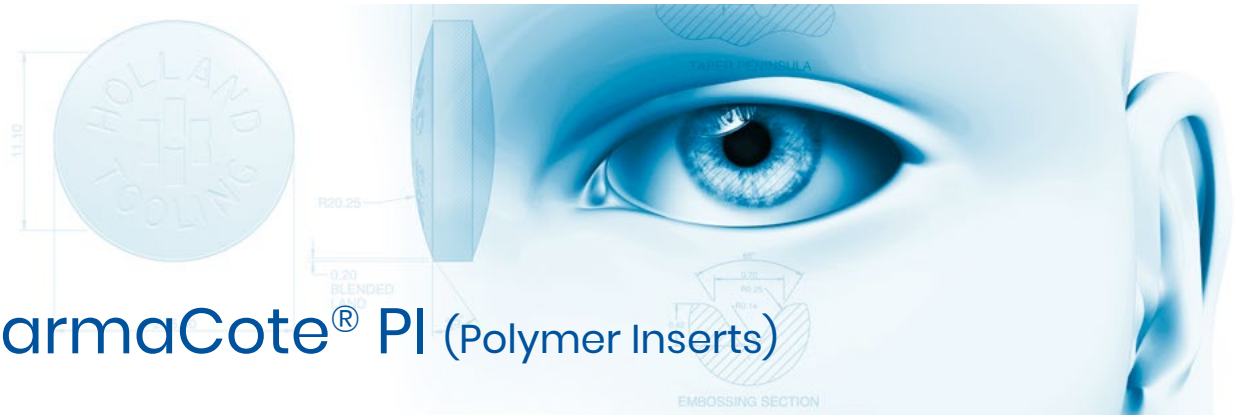
Applied to HPG-P & HPG-SS.
Suitable for both punches & dies.
All over coating supplied as standard.
Tip & barrel option also available.

PharmaCote® RS (Resilient Surface)

Description	A dark silver coloured coating applied to the tip of the punch, with superb wear resistant properties but also good resistance to corrosion.
Features	Very smooth finish. Tip Face Thickness: 2-4 microns. Hardness: 3000 Hv (est).
Benefits	Our most wear resistant coating with a very hard surface layer. More than 3 times the hardness of hard chromium. Extremely easy to clean & maintain using an ultrasonic bath & light automated polishing.
Application	Applied to HPG-P & HPG-SS. Punch tip only coating - to prevent excessive wear to compression rollers.

PharmaCote® DX (Dymonic Coating)

Description	A black coating which helps to reduce sticking of formulation to punch tip surfaces. Improves corrosion & wear resistance.
Features	Amorphous structure. Non reactive coating. Very smooth surface. Chemically inert. Tip Face Thickness: 2-8 microns. Hardness: 1400Hv (est).
Benefits	A good non-stick coating for punches. Good resistance to corrosive products. Good resistance to wear. Easy to clean & maintain using an ultrasonic bath & light automated polishing. Black colour can help with tooling identification.
Application	Applied to HPG-P & HPG-SS. Punch tip & barrel only coating.



PharmaCote® PI (Polymer Inserts)

Description

A polymer or elastomer insert cut to match the tip shape which reduces sticking of the formulation to the punch face.

Features

May be made from a choice of materials (see below).
Thickness: PTFE, Vulkollan & Adiprene - 1.5mm & 2mm.
Carbon & Clear Silicate - 2mm only.
Hardness: variable with material choice.

Benefits

A good anti-stick solution especially for effervescent products.
Inserts are replaceable at low cost.

Application

Suitable for Flat Bevelled Edge and Flat Faced punches only.
A modification to the punch tip is required to hold the insert.
in place - Can be used in conjunction with HPG-S, HPG-P & HPG-SS.

PTFE

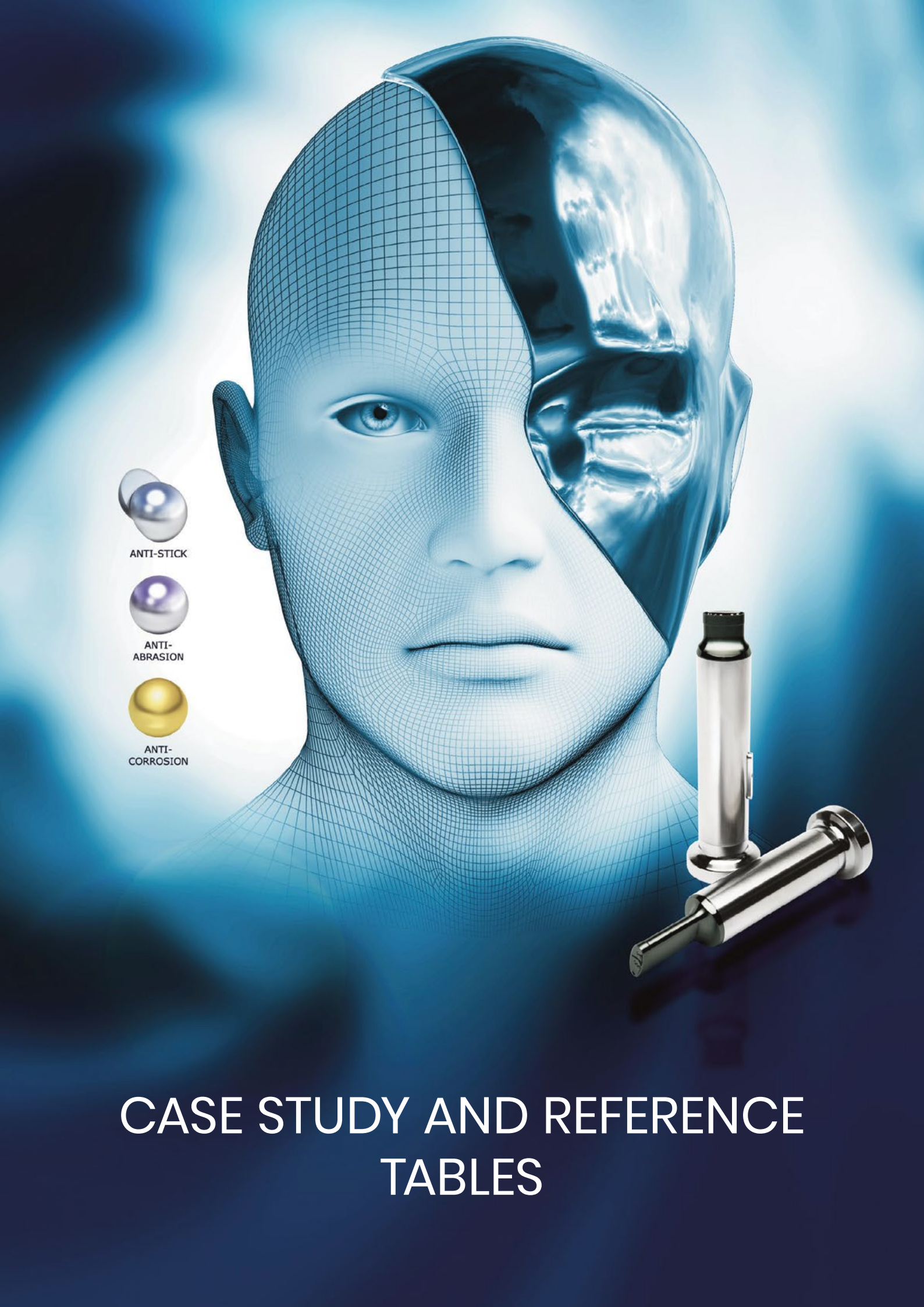
Vulkollan

Adiprene

Carbon

Clear Silicate

Material	Feature	Benefit	Hardness	Tensile Strength	Wear Resistance	Friction Coefficient
PTFE	Hydrophobic material Very smooth Hardest of the insert materials	Can reduce sticking caused by moisture Allows greater cohesion forces in the tablet FDA Compliant	High	Low	Low	Low
Vulkollan	Insert with best wear resistance. Low Deformation, very springy material	Longest lasting insert material. Can reduce sticking.	Low	High	Highest	High
Adiprene	Good wear resistance Smooth material	Combination of the properties of the other 2 insert materials. Good anti-stick properties combined with good wear resistance. Low abrasion - long lasting insert material.	Medium	Medium	Medium	Medium
Carbon	Harder insert material than PTFE Highest wear resistance of PTFE materials	Longer lasting insert material. Carbon Black can transfer (not desirable for white tablets) FDA Compliant	Highest	Highest	High	Low
Clear Silicate	Harder insert material than PTFE	Longer lasting insert material due to higher hardness and compressive strength over PTFE. FDA Compliant	Highest	Highest	Medium	Low



CASE STUDY AND REFERENCE TABLES

CASE STUDY

You Can Save Time and Money By Selecting The Correct Anti-Abrasive Solution

> "We were completely astounded by the increase in tablet output on just one set of tooling."

Kevin Fairhurst,
Production Manager - Thompson & Capper

The User

Thompson & Capper is a contract manufacturer of pharmaceutical and nutritional tablets, based in the UK. They produce over 2.5 billion tablets every year, mainly for clients in Europe.

Thompson & Capper can rightly claim to have been involved in the history of tablet making, and their partnership with I Holland has been longstanding. Over the years, medicines, food stuffs and chemicals have formed the bulk of their work, but, their processes have also included such novelties as tea tablets and tablets used to inflate tennis balls!

The Challenge

I Holland has recently helped Thompson & Capper to make major cost savings on the manufacture of one of their siliceous earth products. The tablets compressed well during the development phase, but it was not until the tablet hit full scale production that it became clear the formulation was extremely abrasive. The first batch produced only 1.5 million tablets on the Manesty D4, 20 station machine, and wear on the punch tips was visible when de-tooling the press. Only 4.5 million tablets were produced per tool set which is far below output levels expected for typical formulations, where tablet output per set would be in the region of 50-60 million tablets.

FIGURE 1: HPG-S punch after producing 4.5 million tablets, showing significant wear across the whole punch tip face and tip straight.

FIGURE 2: RS coated punch these were removed after producing 35 million tablets.

The initial tools supplied were on I Holland's standard steel HPG-S (Holland PharmaGrade® Standard). After Thompson & Capper ran three sets, it was obvious to I Holland that a more sophisticated, wear resistant solution was required. Working with the I Holland Customer Support Group it was agreed to run a set of punches with I Holland's extremely wear resistant PharmaCote® RS coating, applied to HPG-P (Holland PharmaGrade® Premium) steel. A full set was supplied and after producing 35 million tablets, they were still in a useable condition. Operators in Thompson & Capper's production team inspected the condition of the tool set daily, and it was finally agreed to remove the coated tools at 45 million tablets.

According to Kevin Fairhurst, Production Manager at Thompson & Capper, they were surprised by the results: "We were completely astounded by the increase in tablet output on just one set of tooling. Despite an increase in the cost of the tooling for the coated set, we were able to increase output per set by 10 times. Even then, the decision to stop production at that point was based on wear to the compression rollers, rather than tip wear. More significantly, we were able to save on 9 tool changes per set. One tool change taking a whole production shift."

Thompson and Capper has now purchased further sets of PharmaCote® RS coated tooling and is looking to roll it out to other abrasive products as their portfolio expands. They are also considering other solutions from I Holland's PharmaCote® range for their sticky formulations and will be using the TSAR≈ Predict service to facilitate selection of the right coating for these.

The Business Case:

Total increase in cost of tooling = 78%

Total increase in tablet output = 900%

PharmaCote® RS

Description: A distinctive silver blue coloured coating applied to the tip of the punch, with superb wear resistant properties but also good resistance to corrosion.

Features: Very smooth finish

Thickness: 2-4 microns

Hardness: 3000 Hv (est)

Benefits: Our most wear resistant coating due to the very hard surface layer More than 3 times the hardness of Hard Chromium Extremely easy to clean and maintain using an ultrasonic bath and light automated polishing

Application: Applied to HPG-P & HPG-SS Punch tip only coating - to prevent excessive wear to compression rollers

> "We were able to save on 9 tool changes per set. One tool change taking a whole production shift."

Frequently Asked Questions

Q: Can you explain how to minimize picking and sticking during compression?

A: Picking is best dealt with by changing the tablet design as this is normally the root cause of the problem. If the design cannot be changed to reduce picking then an anti-stick coating can be utilised. Alternatively, sticking can be initiated by a number of different root causes and therefore requires more complex solutions. Sometimes slight changes to the design can help reduce sticking but often advanced coating solutions are required.

Q: What rules should be followed when designing or selecting the right tooling, especially when the product is sticky?

A: I Holland's Customer Support Group (CSG) are always available to help guide you through the tablet designing process. We offer many different design based solutions for sticking. Should the product be too sticky for design changes alone to resolve the problem, then CSG use the TSAR Predict service which will predict the single particle adhesion force of the ingredients within the formulation. This in turn will then help us to offer a scientifically selected anti-stick coating solution.

Q: Do you have any tips for handling sticky products such as Ibuprofen or similar? Do you recommend certain tooling/coatings?

A: We have great results with our PharmaCote® coatings but we look at each case on its own merit using the free of charge TSAR Predict service as this allows us to take into account all the possible parameters that might be causing the sticking. Please contact I Holland Customer Support Group for further information.

Q: Is it possible to repair hard chrome coating in used tools?

A: We do not recommend repairing any of the coatings as more damage can be caused. With hard chrome, for example, each time you apply this coating it reduces the steel's ability to resist breakage. This is because when hard chromium is applied hydrogen embrittlement occurs which creates a brittle structure within the steel.

Q: Is it possible for the coatings to fall off the tooling?

A: If the coating is applied incorrectly then it is possible to have adhesion problems. I Holland carry out numerous adhesion tests to the coatings we apply. This includes both destructive and non-destructive testing of the coating which identify if adhesion does not meet our high standards. We only quality assure the very highest level of coating adhesion for tablet tooling. Correct maintenance in line with I Holland's 7 Step process will also help increase the life of the coating.

Q: Can coatings be polished?

A: We recommend light automated polishing for coated tooling. The use of the MF Polishing machine will uniformly polish tooling and therefore reduce the possibility of damaging the coating. On page 26 of this brochure you can see the number of MF polishing cycles that can be carried out without causing the coating to degrade.

Q: Does TSAR tell us if a new formulation is sticky or not?

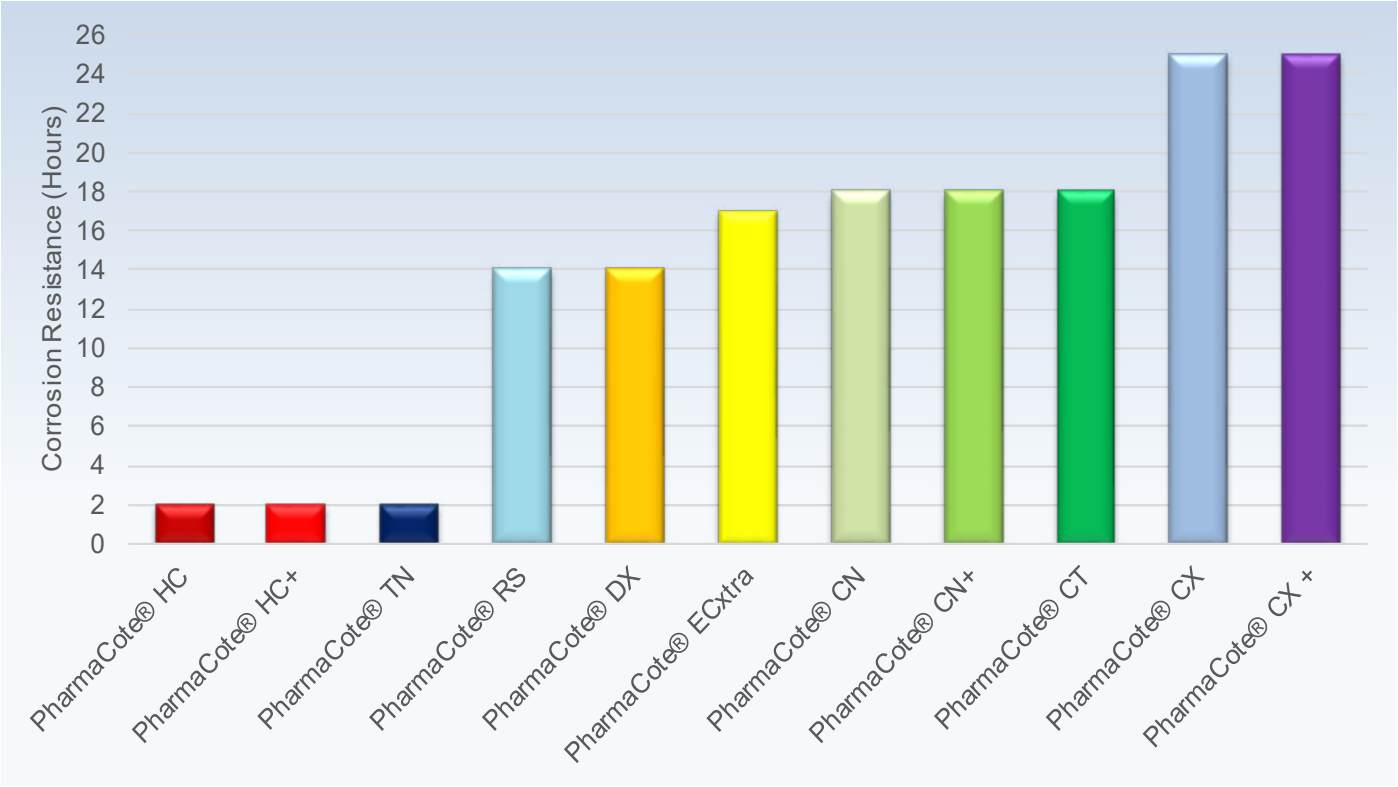
A: TSAR predict will identify the coating with the lowest particle adhesion, it was not designed to predict if a new formulation or product is potentially sticky.

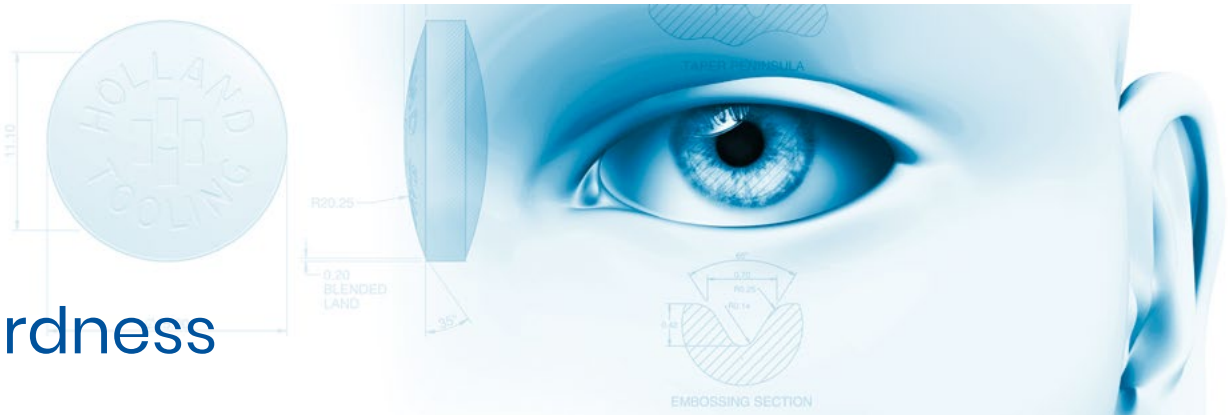
Coating Summary

COATING	Tooling Type		Steel Type		
	PUNCHES	DIES	HPG-S	HPG-P	HPG-SS
PharmaCote® HC (Standard)	✓	✓	✓	✓	✓
PharmaCote® HC (Barrel & Tip)	✓		✓	✓	✓
PharmaCote® HC (All Over)	✓	✓	✓	✓	✓
PharmaCote® HC (Tip Only)	✓		✓	✓	✓
PharmaCote® HC (Head, Neck & barrel)	✓		✓	✓	✓
PharmaCote® HC+ (Standard)	✓		✓	✓	✓
PharmaCote® HC+ (Barrel & Tip)	✓		✓	✓	✓
PharmaCote® HC+ (All Over)	✓		✓	✓	✓
PharmaCote® HC+ (Tip Only)	✓		✓	✓	✓
PharmaCote® EC^{xtra} (Standard) IMPROVED	✓		✓		
PharmaCote® CN (Standard)	✓	✓		✓	✓
PharmaCote® CN (Barrel & Tip)	✓			✓	✓
PharmaCote® CN+ (Standard)	✓			✓	✓
PharmaCote® CN+ (Barrel & Tip)	✓			✓	✓
PharmaCote® CX (Standard)	✓			✓	✓
PharmaCote® CX (Barrel & Tip)	✓			✓	✓
PharmaCote® CX+ (Standard)	✓			✓	✓
PharmaCote® CX+ (Barrel & Tip)	✓			✓	✓
PharmaCote® CT (Standard)	✓			✓	
PharmaCote® CT (Barrel & Tip)	✓			✓	
PharmaCote® TN (Standard)	✓	✓		✓	✓
PharmaCote® TN (Barrel & Tip)	✓			✓	✓
PharmaCote® DX (Tip Only)	✓		✓	✓	✓
PharmaCote® RS (Tip Only)	✓			✓	✓

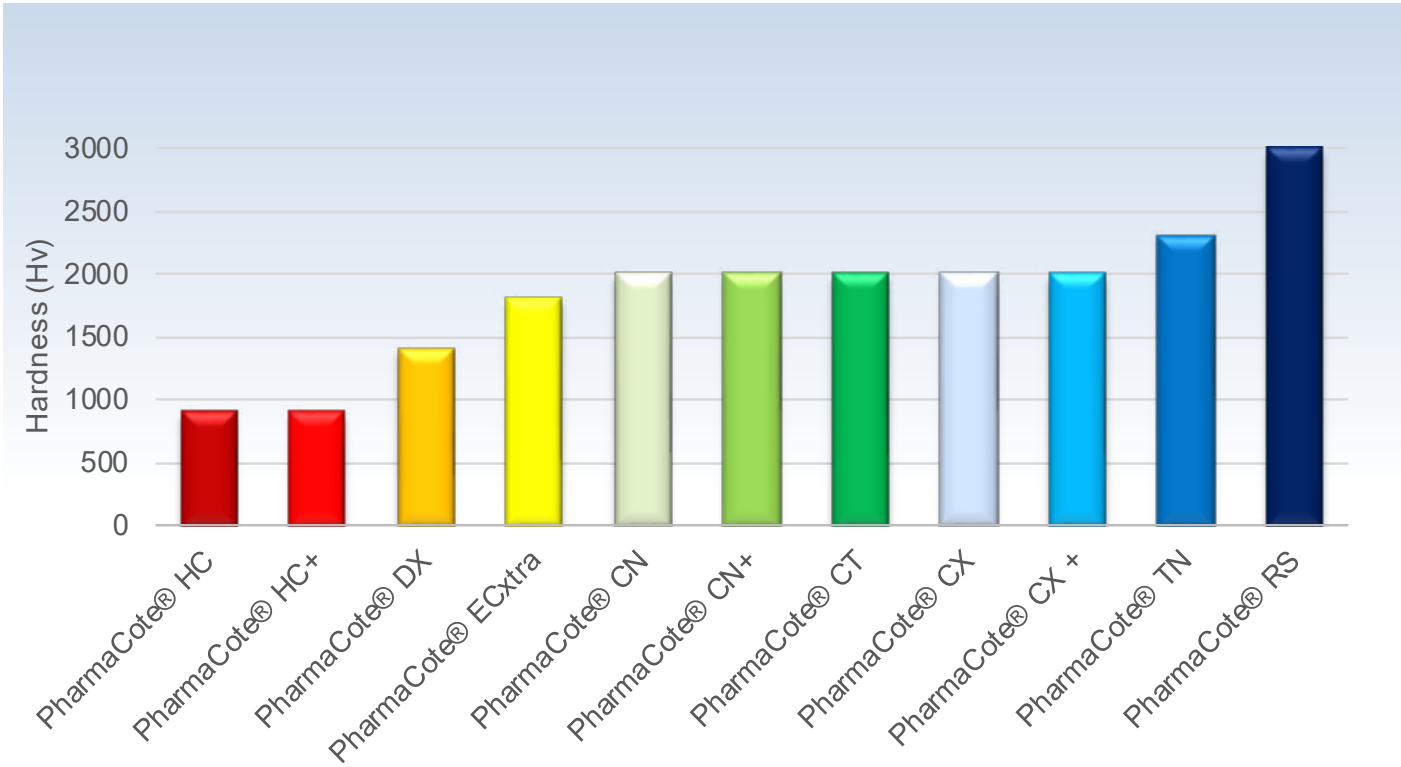
Corrosion Resistance

Corrosion Resistance in Hours

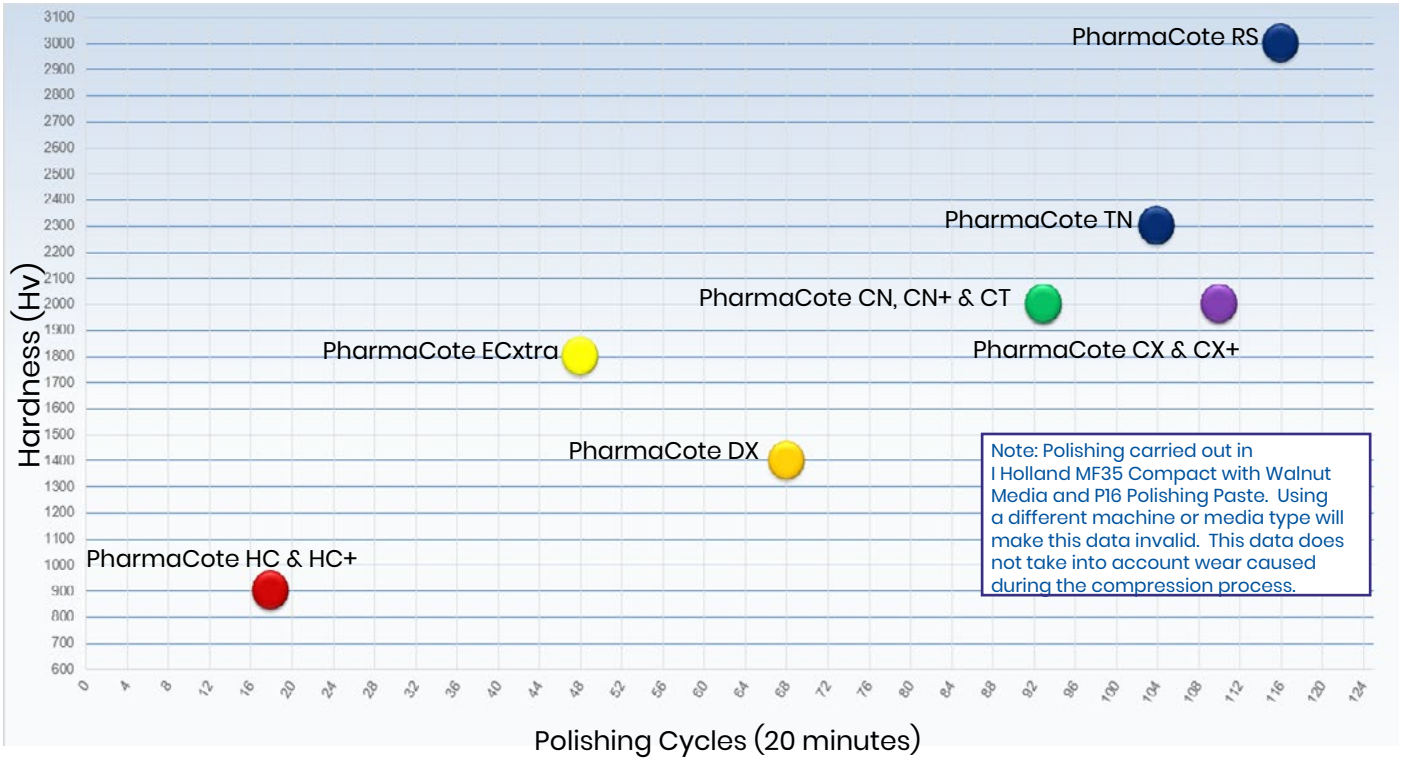




Hardness


Hardness (Hv)
3000
2500
2000
1500
1000
500
0
PharmaCote® HC
PharmaCote® HC+
PharmaCote® DX
PharmaCote® ECxtra
PharmaCote® CN
PharmaCote® CN+
PharmaCote® CT
PharmaCote® CX
PharmaCote® CX +
PharmaCote® TN
PharmaCote® RS

PharmaCote®
Automated Polishing Guide

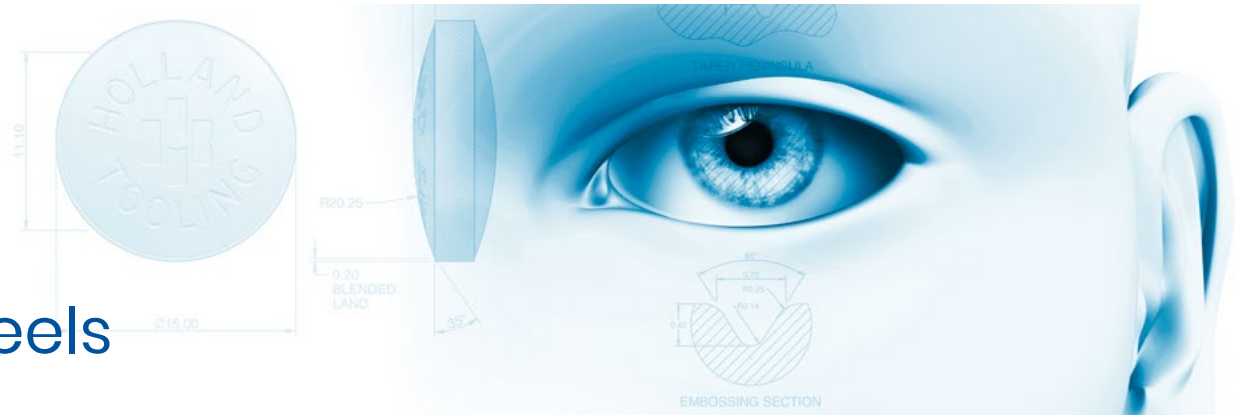


The chart above shows the number of automated polishing cycles each coating underwent before initial signs of wear were evident. Please note that manual polishing operations will remove coatings much more quickly.

MF Automated Polisher

MICRO-FINE POLISHING OF TABLET PUNCHES

In order to maintain PharmaCote® coatings to an optimum finish, I Holland recommends the use of the MF automated polisher series. The MF polishing range allows you to polish dull and discoloured punches to a micro-fine, high quality finish using a drag finishing process. This range covers varying space and capacity requirements from worktop mountable units to large polishers capable of taking 70 punches per cycle.



Steels

There are thousands of steel types available but only a few meet the complex design and functional requirements of tablet tooling. Chemical composition of the steel is only one part of the overall equation, material selection must always be considered alongside good tablet design for strong punch cups and punch tip edges.

To optimise the material and its properties, other processes are required such as:

- Steel refinement (ESR – Electro slag re-melting)
- Optimal heat treatment
- Treatments and coatings
- Powder Metallurgy

All PharmaGrade materials are highly refined to our own specifications and this quality is provided at no additional cost to our customers giving increased strength and wear resistance to tablet tooling.

Steel Refinement - ESR

I Holland's PharmaGrade ESR material (HPG-S & HPG-P) has a homogeneous carbide structure which is distributed evenly throughout the steel. This provides benefits for the end user such as increased tool strength, extended tooling life over conventional (non-refined) steel and coating uniformity.

Powder Metallurgy

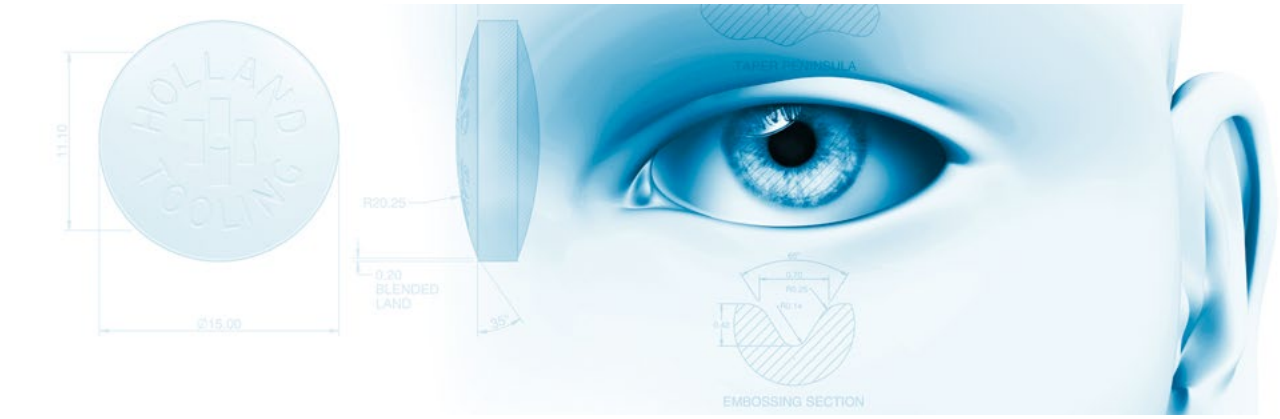
I Holland offers two specialist powder metallurgy steels (HPG-MP & HPG-MD) each offering a uniform carbide distribution, small carbide size and extremely high wear resistance when compared to HPG-S and HPG-P. Powder Metallurgy steels are recommended for extremely abrasive products.

Cross Sections
Showing Carbide Distribution

Conventional Steel

Holland PharmaGrade
HPG-S & HPG-P

Holland PharmaGrade Steels
HPG-MP & HPG-MD



This brochure details materials that are currently available for I Holland tooling. The Research and Development Team is constantly working on the development of new materials.

For further information on our R&D activity, please contact info@iholland.co.uk.

I HOLLAND®
TABLETTING SCIENCE

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